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(54) Title: **ENDOSCOPE WITH ADJACENTLY POSITIONED GUIDING APPARATUS**

(57) Abstract: An endoscope with guiding apparatus is provided. The endoscope has an elongate body with a steerable distal portion, an automatically controlled portion, a flexible and passively manipulated proximal portion, and an externally controlled and manipulatable guiding apparatus. The guiding apparatus may be positioned within the endoscope or may be positioned adjacent to the endoscope. An interlocking device is provided to slidably interlock the guiding apparatus and the endoscope. When the guide is in a flexible state, it can conform to a curve or path defined by the steerable distal portion and the automatically controlled portion. The guide can be then be selectively rigidized to assume that curve or path. Once rigidized, the endoscope can be advanced along the guide in a monorail or "piggy-back" fashion so that the flexible proximal portion follows the curve held by the guide until the endoscope reaches a next point of curvature within a body lumen.

## ENDOSCOPE WITH ADJACENTLY POSITIONED GUIDING APPARATUS

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. Patent Application Serial No. 10/087,100 entitled "Endoscope With Guiding Apparatus" filed March 1, 2002, which is a continuation-in-part of U.S. Patent Application Serial No. 09/969,927 entitled "Steerable Segmented Endoscope and Method of Insertion" filed October 2, 2001, which is a continuation-in-part of U.S. Patent Application Serial No. 09/790,204 entitled "Steerable Endoscope and Improved Method of Insertion" filed February 20, 2001, which claims the benefit of priority to U.S. Provisional Patent Application Serial No. 60/194,140 entitled the same and filed April 3, 2000, all of which are incorporated herein by reference in their entirety.

### TECHNICAL FIELD OF THE INVENTION

[0002] The present invention relates generally to endoscopes and endoscopic procedures. More particularly, it relates to a method and apparatus to facilitate insertion of a flexible endoscope along a tortuous path, such as for colonoscopic examination and treatment.

### BACKGROUND OF THE INVENTION

[0003] An endoscope is a medical instrument for visualizing the interior of a patient's body. Endoscopes can be used for a variety of different diagnostic and interventional procedures, including colonoscopy, bronchoscopy, thoracoscopy, laparoscopy and video endoscopy.

[0004] Colonoscopy is a medical procedure in which a flexible endoscope, or colonoscope, is inserted into a patient's colon for diagnostic examination and/or surgical treatment of the colon. A standard colonoscope is typically 135-185 cm in length and 12-19 mm in diameter, and includes a fiberoptic imaging bundle or a miniature camera located at the instrument's tip, illumination fibers, one or two instrument channels that may also be used for insufflation or irrigation, air and water channels, and vacuum channels. The colonoscope is inserted via the patient's anus and is advanced through the colon, allowing direct visual examination of the colon, the ileocecal valve and portions of the terminal ileum.

[0005] Insertion of the colonoscope is complicated by the fact that the colon represents a tortuous and convoluted path. Considerable manipulation of the colonoscope is

often necessary to advance the colonoscope through the colon, making the procedure more difficult and time consuming and adding to the potential for complications, such as intestinal perforation. Steerable colonoscopes have been devised to facilitate selection of the correct path though the curves of the colon. However, as the colonoscope is inserted farther and farther into the colon, it becomes more difficult to advance the colonoscope along the selected path. At each turn, the wall of the colon must maintain the curve in the colonoscope. The colonoscope rubs against the mucosal surface of the colon along the outside of each turn. Friction and slack in the colonoscope build up at each turn, making it more and more difficult to advance, withdraw, and loop the colonoscope. In addition, the force against the wall of the colon increases with the buildup of friction. In cases of extreme tortuosity, it may become impossible to advance the colonoscope all of the way through the colon.

[0006] Steerable endoscopes, catheters and insertion devices for medical examination or treatment of internal body structures are described in the following U.S. patents, the disclosures of which are hereby incorporated by reference in their entirety: 4,543,090; 4,753,223; 5,337,732; 5,337,733; 5,383,852; 5,487,757; 5,624,381; 5,662,587; and 5,759,151.

#### SUMMARY OF THE INVENTION

[0007] Accordingly, an improved endoscopic apparatus is disclosed herein for the examination of a patient's colon or other internal bodily cavities with minimal impingement upon bodily cavities or upon the walls of the organs. A steerable endoscope having an elongate body with a manually or selectively steerable distal portion, an automatically controlled portion, which may be optionally omitted from the device, a flexible and passively manipulated proximal portion, and an externally controlled and manipulatable tracking rod or guide is described below. The guide may be slidably positioned within a lumen of an endoscope or it may be positioned adjacent to the endoscope such that the guide and the endoscope slide relative to one another along or within a channel located on an outer surface of the endoscope. The endoscope may be similarly positioned in a channel located along the guide.

[0008] In one variation, an interlocking device is used to receive and slidably interlock the endoscope and guide. The interlocking device has a proximal end, a distal end, and a lumen therethrough. It may also have a segregating member disposed within its lumen for defining separate compartments for receiving the endoscope and guide. The interlocking device may be integrated into a single unit with an axial motion transducer, or it may be a stand-alone unit positioned proximally, distally, or adjacent to an axial motion transducer. It

may be affixed to a table upon which the patient lies, or alternatively, may be free to slide along the length of the guide or endoscope to accommodate their relative movement.

[0009] The interlocking device slidably interlocks the guide and endoscope by providing pressure sufficient to releaseably secure the guide or endoscope within a channel positioned along the outer surface of the corresponding endoscope or guide (e.g., much like a pressure lock zipper). This may be accomplished in any number of ways. In some variations manual pressure is applied to the outer surface of the interlocking device, and in other variations, pressure is applied automatically and controlled remotely by a processor. In other variations, the lumen diameter of the interlocking device is configured such that no additional pressure need be applied. In yet another variation, magnetism is used to interlock the endoscope and guide.

[0010] Any number of channel configurations may be used with the interlocking device. For example, the guide may be adapted to fit within a channel positioned along the outer surface of the endoscope, or the endoscope may be adapted to fit within a channel positioned along the outer surface of the guide. The channel need not be continuous along the outer length of the endoscope or guide; it may be attached only to a portion thereof. It may be slidable, comprised of a series of semi-circular shaped rings, or be partially open or completely closed.

[0011] In one variation, the endoscope or guide has a projecting member and the corresponding guide or endoscope has a locking member for receiving the projecting member therein. The projecting member may be disposed along the entire length of the guide or endoscope, or only a portion thereof. Similarly, the projecting member may be slidable along the outer surface of the endoscope or guide.

[0012] In another variation, multiple channels are provided along the outer surface of the endoscope or guide. These channels may be used for insertion of additional guides, tools, devices, or drugs for delivery. The channels may be any number of sizes to accommodate the varying circumferences of the various guides, tools, or devices. The channels may also be slidable, removable, or affixed to at least a portion of the outer surface of the guide or endoscope. The channels may be continuous or discontinuous along the length of endoscope or guide.

[0013] The channel may be made using any number of materials and may be attached to the endoscope or guide using any number of methods. For example, the channel may be made of the same material as the endoscope or guide covering and be integral thereto. In other variations, the channel may be attached using adhesives like bonding formulas, resins,

glues, and cements, or mechanical fasteners like clamps. The channel may also be attached by crimping it to the guide or endoscope, or snap fitting it thereon. Once the endoscope, guide, and any other additional tools become slidably interlocked via the interlocking device, the endoscope may be advanced into a patient's body cavity.

[0014] In operation, the steerable distal portion of the endoscope may be first advanced into a patient's rectum via the anus. The endoscope may be simply advanced, either manually or automatically by a motor, until the first curvature is reached. At this point, the steerable distal portion may be actively controlled by the physician or surgeon to attain an optimal curvature or shape for advancement of the endoscope. The optimal curvature or shape is considered to be the path which presents the least amount of contact or interference from the walls of the colon. In one variation, once the desired curvature has been determined, the endoscope may be advanced further into the colon such that the automatically controlled segments of controllable portion follow the distal portion while transmitting the optimal curvature or shape proximally down the remaining segments of the controllable portion. The operation of the controllable segments will be described in further detail below.

[0015] Alternatively, once the steerable distal portion has been steered or positioned for advancement, the guide may be advanced distally in its flexible state along or within the endoscope until it reaches a distal position, i.e., preferably some point distal of the flexible proximal portion. Regardless whether the optional controllable portion is omitted or not from the device, the guide may be advanced near or to the end of the distal portion. Once the guide has been advanced, it may directly attain and conform to the curvature or shape defined by the steerable distal portion.

[0016] The guide is advanced to the distal end of steerable distal portion or, if the controllable portion is included in the device, the guide may be advanced to the distal end of the controllable portion, or to some point between the two portions. The guide may be advanced to any distal position as long as a portion of guide attains and conforms to the optimal curvature or shape. Prior to advancing the endoscope over the guide, the guide may be left in its flexible state or it may be optionally rigidized, as discussed further below. If left in its flexible state, the guide may possibly provide desirable column strength to the endoscope as it is advanced through the colon over the guide. It is preferable, however, that the guide is rigidized once it has attained and conformed to the curvature. This allows the flexible proximal portion, i.e., the passive portion, to remain flexible and lightweight in structure. As the position of the guide is preferably rigidized and maintained, the endoscope may then be advanced along the guide in a monorail or "piggy-back" fashion so that the

flexible proximal portion follows the curve held by the guide until the endoscope reaches the next point of curvature.

[0017] This process of alternately advancing the guide and the endoscope may be repeated to advance the entire endoscope through the colon while the guide may be alternatively rigidized and relaxed while being advanced distally. While the endoscope is advanced through the colon, the physician or surgeon may stop the advancement to examine various areas along the colon wall using, e.g., an imaging bundle located at the distal end of the endoscope. During such examinations, the guide may be temporarily withdrawn from the endoscope to allow for the insertion of other tools through the guide channel if there is no separate channel defined within the endoscope for the guide. The guide may also be withdrawn through the instrument to any location within the body of the endoscope. In other words, the guide may be withdrawn partially or removed entirely from the endoscope at any time, if desired, because there are no constraints which may limit the travel of the guide through the body of the endoscope. After a procedure has been completed on the colon wall, the tool may be withdrawn from the guide channel and the guide may be reintroduced into the endoscope so that the endoscope may optionally be advanced once again into the colon.

[0018] A further variation on advancing the endoscope may use multiple guides which are alternately rigidized while being advanced distally along a path. Although multiple guides may be used, two guides are preferably utilized. As the endoscopic device approaches a curvature, a first guide may be advanced in a relaxed and flexible state towards the steerable distal end of the device. While being advanced, the first guide preferably conforms to the shape defined by the distal end and the first guide may be subsequently rigidized to maintain this shape. The device may then be advanced further distally along the pathway while riding over the rigidized first guide.

[0019] After the device has been advanced to its new position, a second guide may also be advanced distally in its relaxed state through the device up to the distal end while the first guide is maintained in its rigidized state. The second guide may then conform to the new shape defined by the distal end of the device and become rigidized to maintain this new shape. At this point, the first guide is also preferably maintained in its rigid state until the distal end of the device has been advanced further distally. The first guide may then be relaxed and advanced while the rigidity of the second guide provides the strength for advancing the guide. This procedure may be repeated as necessary for negotiating the pathway.

[0020] To withdraw the endoscope from within the colon, the procedure above may be reversed such that the withdrawal minimally contacts the walls of the colon. Alternatively,

the guide may simply be removed from the endoscope while leaving the endoscope within the colon. Alternatively, the guide may be left inside the endoscope in the relaxed mode. The endoscope may then be simply withdrawn by pulling the proximal portion to remove the device. This method may rub or contact the endoscope upon the walls of the colon, but any impingement would be minimal.

[0021] The selectively steerable distal portion can be selectively steered or bent up to a full 180° bend in any direction. A fiberoptic imaging bundle and one or more illumination fibers may extend through the body from the proximal portion to the distal portion. The illumination fibers are preferably in communication with a light source, i.e., conventional light sources, which may be positioned at some external location, or other sources such as LEDs. Alternatively, the endoscope may be configured as a video endoscope with a miniaturized video camera, such as a CCD camera, positioned at the distal portion of the endoscope body. The video camera may be used in combination with the illumination fibers. Optionally, the body of the endoscope may also include one or two access lumens that may optionally be used for insufflation or irrigation, air and water channels, and vacuum channels, etc. Generally, the body of the endoscope is highly flexible so that it is able to bend around small diameter curves without buckling or kinking while maintaining the various channels intact. The endoscope can be made in a variety of other sizes and configurations for other medical and industrial applications.

[0022] The optional controllable portion is composed of at least one segment and preferably several segments which may be controllable via a computer and/or controller located at a distance from the endoscope. Each of the segments preferably have an actuator mechanically connecting adjacent segments to allow for the controlled motion of the segments in space. The actuators driving the segments may include a variety of different types of mechanisms, e.g., pneumatic, vacuum, hydraulic, electromechanical motors, drive shafts, etc. If a mechanism such as a flexible drive shaft were utilized, the power for actuating the segments would preferably be developed by a generator located at a distance from the segments, i.e., outside of a patient during use, and in electrical and mechanical communication with the drive shaft. A proximal portion comprises the rest of the endoscope and preferably a majority of the overall length of the device. The proximal portion is preferably a flexible tubing member which may conform to an infinite variety of shapes. It may also be covered by a polymeric covering optionally extendable over the controllable portion and the steerable distal portion as well to provide a smooth transition between the controllable segments and the flexible tubing of the proximal portion. The controllable

portion may be optionally omitted from the endoscope. A more detailed description on the construction and operation of the segments may be found in U.S. Pat. Application Serial No. 09/969,927 entitled "Steerable Segmented Endoscope and Method of Insertion" filed October 2, 2001, which has been incorporated by reference in its entirety.

[0023] A proximal handle may be attached to the proximal end of the proximal portion and may include imaging devices connected to the fiberoptic imaging bundle for direct viewing and/or for connection to a video camera or a recording device. The handle may be connected to other devices, e.g., illumination sources and one or several luer lock fittings for connection to various instrument channels. The handle may also be connected to a steering control mechanism for controlling the steerable distal portion. The handle may optionally have the steering control mechanism integrated directly into the handle, e.g., in the form of a joystick, conventional disk controller using dials or wheels, etc. An axial motion transducer may also be provided for measuring the axial motion, i.e., the depth change, of the endoscope body as it is advanced and withdrawn. The axial motion transducer can be made in many possible configurations. As the body of the endoscope slides through the transducer, it may produce a signal indicative of the axial position of the endoscope body with respect to the fixed point of reference. The transducer may use various methods for measuring the axial position of the endoscope body.

[0024] The guide is generally used to impart a desired curvature initially defined by the steerable portion and/or by the optional controllable portion to the passive proximal portion when the endoscope is advanced. If advanced into the steerable portion, the guide is preferably advanced to or near the distal tip of the portion. It is also used to impart some column strength to the proximal portion in order to maintain its shape and to prevent any buckling when axially loaded. Preferably, the guide is slidably disposed within the length of the endoscope body and may freely slide entirely through the passive proximal portion, through the controllable portion, and the steerable distal portion. The extent to which the guide may traverse through the endoscope body may be varied and adjusted according to the application, as described above. Furthermore, the proximal end of the guide may be routed through a separate channel to a guide controller which may be used to control the advancement and/or withdrawal of the guide and which may also be used to selectively control the rigidity of the guide as controlled by the physician.

[0025] The structure of the guide may be varied according to the desired application. The following descriptions of the guide are presented as possible variations and are not intended to be limiting in their structure. For instance, the guide may be comprised of two



coaxially positioned tubes separated by a gap. Once the guide has been placed and has assumed the desirable shape or curve, a vacuum force may be applied to draw out the air within the gap, thereby radially deforming one or both tubes such that they come into contact with one another and lock their relative positions.

[0026] Another variation on the guide is one which is rigidizable by a tensioning member. Such a guide may be comprised of a series of individual segments which are rotatably interlocked with one another in series. Each segment may further define a common channel through which a tensioning member may be positioned while being held between a proximal and a distal segment. During use, the tensioning member may be slackened or loosened enough such that the guide becomes flexible enough to assume a shape or curve defined by the endoscope. When the guide is desirably situated and has assumed a desired shape, the tensioning member may then be tensioned, thereby drawing each segment tightly against one another to hold the desired shape.

[0027] Another variation may use a guide that is comprised of interlocking ball-and-socket type joints which are gasketed at their interfaces. Such a design may utilize a vacuum pump to selectively tighten and relax the individual segments against one another. Other variations may include alternating cupped segments and ball segments, a series of collinear sleeve-hemisphere segments, as well as other designs which may interfit with one another in series. Such a guide may be tightened and relaxed either by tensioning members or vacuum forces.

[0028] A further variation on the guide is a coaxially aligned stiffening member. This assembly may include a first subassembly comprising a number of collinearly nested segments which may be held by a tensioning member passing through each segment. The first subassembly may be rigidized from a flexible or flaccid state by pulling on this tensioning member. A second subassembly may comprise a number of annular segments also collinearly held relative to one another with one or more tensioning members passing through each annular segment. The second subassembly preferably defines a central area in which the first nested subassembly may be situated coaxially within the second subassembly. The first subassembly is preferably slidably disposed relative to the second subassembly thereby allowing each subassembly to be alternately advanced in a flexible state and alternately rigidized to allow the other subassembly to be advanced. This design presents a small cross-section relative to the endoscope or device through which it may be advanced.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- [0029] Fig. 1 shows a representation of a conventional endoscope in use.
- [0030] Fig. 2 shows a variation of an endoscopic device of the present invention.
- [0031] Fig. 3A shows a side view of an endoscopic device variation with the outer layers removed to reveal a guiding apparatus disposed within.
- [0032] Figs. 3B and 3C show cross-sectional views of various examples for obstructing the guide lumen of the endoscope.
- [0033] Figs. 4A to 4C show cross-sectional views of various examples of guiding apparatus which may be used to guide an endoscope.
- [0034] Figs. 5A and 5B show the cross-sectioned end and side views, respectively, of a guiding apparatus with a vacuum-actuated rigidizing variation.
- [0035] Figs. 6A and 6B show the cross-sectioned end and side views, respectively, of a guiding apparatus with a tensioning or pre-tensioned element for rigidizing the guide.
- [0036] Figs. 7A and 7B show the cross-sectioned end and side views, respectively, of a guiding apparatus with a segmented vacuum-actuated rigidizing variation.
- [0037] Figs. 8A and 8B show the cross-sectioned end and side views, respectively, of a guiding apparatus with interconnecting jointed segments for rigidizing the guide.
- [0038] Figs. 9A to 9C show end, side, and cross-sectioned views, respectively, of another variation on the guiding apparatus.
- [0039] Fig. 10 shows the cross-sectioned side view of another variation on the guiding apparatus having alternating bead and sleeve segments.
- [0040] Fig. 11A shows a side view of a nested guiding apparatus which is part of a coaxial stiffening assembly.
- [0041] Fig. 11B shows a side view of an annular guiding apparatus which is also part of the coaxial stiffening assembly.
- [0042] Fig. 11C shows the combination of the guides from Figs. 11A and 11B.
- [0043] Figs. 12A to 12H illustrate a representative example of advancing an endoscope through a patient's colon using a guiding apparatus to assist in advancing the endoscope.
- [0044] Figs. 13A and 13B show a variation on the withdrawal of the endoscope with or without the guiding apparatus for the selective treatment of sites along the patient's colon.
- [0045] Figs. 14A to 14C illustrate a representative example of advancing an endoscope through a tortuous path using the coaxial guiding apparatus shown in Figs. 11A to 11C.

- [0046] Figs. 15A to 15E illustrate another variation of advancing an endoscope through a tortuous path using multiple guiding apparatuses.
- [0047] Fig. 16A illustrates another variation of the invention, where the guiding apparatus and endoscope are slidably interlocked adjacent to one another.
- [0048] Fig. 16B illustrates how an interlocking device may be used to slidably interlock the endoscope and the guiding apparatus.
- [0049] Fig. 16C illustrates how a segregating member may be disposed within the lumen of the interlocking device for defining separate compartments for receiving the guiding apparatus and endoscope, and further illustrates several possible configurations of the segregating member.
- [0050] Fig. 16D illustrates how the guiding apparatus and endoscope may be advanced distally into the interlocking device.
- [0051] Fig. 16E illustrates one variation of the interlocking device where the guiding apparatus and endoscope are pressure fit therein.
- [0052] Figs. 17A to 17H illustrate sample channel configurations for use with one variation of the present invention.
- [0053] Fig. 18 illustrates an example of how an endoscope and guiding apparatus may be advanced into a patient's colon using the interlocking device of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

[0054] Fig. 1 shows a prior art colonoscope 10 being employed for a colonoscopic examination of a patient's colon C. The colonoscope 10 has a proximal handle 16 and an elongate body 12 with a steerable distal portion 14. The body 12 of the colonoscope 10 has been lubricated and inserted into the colon C via the patient's anus A. Utilizing the steerable distal portion 14 for guidance, the body 12 of the colonoscope 10 has been maneuvered through several turns in the patient's colon C to the ascending colon G. Typically, this involves a considerable amount of manipulation by pushing, pulling and rotating the colonoscope 10 from the proximal end to advance it through the turns of the colon C. After the steerable distal portion 14 has passed, the wall of the colon C maintains the curve in the flexible body 12 of the colonoscope 10 as it is advanced. Friction develops along the body 12 of the colonoscope 10 as it is inserted, particularly at each turn in the colon C. Because of the friction, when the user attempts to advance the colonoscope 10, the body 12' tends to move outward at each curve, pushing against the wall of the colon C, which exacerbates the problem by increasing the friction and making it more difficult to advance the colonoscope

10. On the other hand, when the colonoscope 10 is withdrawn, the body 12" tends to move inward at each curve taking up the slack that developed when the colonoscope 10 was advanced. When the patient's colon C is extremely tortuous, the distal end of the body 12 becomes unresponsive to the user's manipulations, and eventually it may become impossible to advance the colonoscope 10 any farther. In addition to the difficulty that it presents to the user, tortuosity of the patient's colon also increases the risk of complications, such as intestinal perforation.

[0055] Fig. 2 shows a variation of the steerable endoscope 20 of the present invention. The endoscope 20 has an elongate body 21 with a manually or selectively steerable distal portion 24, an automatically controlled portion 28, which may be optionally omitted from the device, a flexible and passively manipulated proximal portion 22, and an externally controlled and manipulatable tracking rod or guide 36 which may be slidably positioned within the endoscope 20.

[0056] The selectively steerable distal portion 24 can be selectively steered or bent up to a full 180° bend in any direction 26, as shown in the figure. A fiberoptic imaging bundle 40 and one or more illumination fibers 42 may extend through the body 21 from the proximal portion 22 to the distal portion 24. Alternatively, the endoscope 20 may be configured as a video endoscope with a miniaturized video camera, such as a CCD camera, positioned at the distal portion 24 of the endoscope body 21. The images from the video camera can be transmitted to a video monitor by a transmission cable or by wireless transmission where images may be viewed in real-time or recorded by a recording device onto analog recording medium, e.g., magnetic tape, or digital recording medium, e.g., compact disc, digital tape, etc. Optionally, the body 21 of the endoscope 20 may include one or two access lumens 38 that may optionally be used for illumination fibers for providing a light source, insufflation or irrigation, air and water channels, and vacuum channels. Generally, the body 21 of the endoscope 20 is highly flexible so that it is able to bend around small diameter curves without buckling or kinking while maintaining the various channels intact. When configured for use as a colonoscope, the body 21 of the endoscope 20 may range typically from 135 to 185 cm in length and about 13-21 mm in diameter. The endoscope 20 can be made in a variety of other sizes and configurations for other medical and industrial applications.

[0057] The optional controllable portion 28 is composed of at least one segment 30, and preferably several segments 30, which may be controllable via a computer and/or controller located at a distance from the endoscope 20. Each of the segments 30 preferably have an actuator mechanically connecting adjacent segments 30 to allow for the controlled

motion of the segments 30 in space. The actuators driving the segments 30 may include a variety of different types of mechanisms, e.g., pneumatic, hydraulic, electromechanical motors, "off board" powered drive shafts, etc. A proximal portion 22 comprises the rest of the endoscope 20 and preferably a majority of the overall length of the device 20. Proximal portion 20 is preferably a flexible tubing member which may conform to an infinite variety of shapes. It may also be covered by a polymeric covering 39 optionally extendable over controllable portion 28 and steerable distal portion 24 as well to provide a smooth transition between the controllable segments 30 and the flexible tubing of proximal portion 22. The proximal portion 22 may be made from a variety of materials such as thermoset and thermoplastic polymers which are used for fabricating the tubing of conventional endoscopes.

[0058] A proximal handle 32 may be attached to the proximal end of the proximal portion 22. The handle 32 may include an ocular 33 connected to the fiberoptic imaging bundle 42 for direct viewing. The handle 32 may otherwise have a connector for connection to a video camera, e.g., a CCD camera, or a recording device. The handle 32 may be connected to an illumination source 43 by an illumination cable 44 that is connected to or continuous with the illumination fibers 42. One or several luer lock fittings 34 may be located on the handle 32 and connected to the various instrument channels.

[0059] The handle 32 is connected to an electronic motion controller 45 by way of a controller cable 46. A steering control 47 may be connected to the electronic motion controller 45 by way of a second cable 48 or it may optionally be connected directly to the handle 32. Alternatively, the handle may have the steering control mechanism integrated directly into the handle, e.g., in the form of a joystick, conventional disk controllers such as dials or wheels, etc. The steering control 47 allows the user to selectively steer or bend the selectively steerable distal portion 26 of the body 21 in the desired direction. The steering control 47 may be a joystick controller as shown, or other known steering control mechanism. The electronic motion controller 45 controls the motion of the automatically controlled proximal portion 28 of the body 21. The electronic motion controller 45 may be implemented using a motion control program running on a microcomputer or using an application-specific motion controller. Alternatively, the electronic motion controller 45 may be implemented using, e.g., a neural network controller.

[0060] An axial motion transducer 49 may be provided for measuring the axial motion, i.e., the depth change, of the endoscope body 21 as it is advanced and withdrawn. The axial motion transducer 49 can be made in many possible configurations. For example, the axial motion transducer 49 in Fig. 2 is configured as a ring 49 that may surround the body

21 of the endoscope 20. The axial motion transducer 49 is preferably attached to a fixed point of reference, such as the surgical table or the insertion point for the endoscope 20 on the patient's body. As the body 21 of the endoscope 20 slides through the axial motion transducer 49, it produces a signal indicative of the axial position of the endoscope body 21 with respect to the fixed point of reference and sends a signal to the electronic motion controller 45 by telemetry or by a cable. The axial motion transducer 49 may use optical, electronic or mechanical methods to measure the axial position of the endoscope body 21.

[0061] Similarly, when the endoscope body 21 is withdrawn proximally, each time the endoscope body 21 is moved proximally by one unit, each section in the automatically controlled proximal portion 28 is signaled to assume the shape of the section that previously occupied the space that it is now in. The curve propagates distally along the length of the automatically controlled proximal portion 28 of the endoscope body 21, and the shaped curve appears to be fixed in space, as the endoscope body 21 withdraws proximally. Alternatively, the segments of controlled portion 28 could be made to become flaccid and the withdrawal would then be passive.

[0062] Whenever the endoscope body 21 is advanced or withdrawn, the axial motion transducer 49 detects the change in position and the electronic motion controller 45 propagates the selected curves proximally or distally along the controllable portion 28 of the endoscope body 21 to maintain the curves in a spatially fixed position. The axial motion transducer 49 also allows for the incrementing of a current depth within the colon C by the measured change in depth. This allows the endoscope body 21 to be guided through tortuous curves without putting unnecessary force on the wall of the colon C. As mentioned above, such a segmented body 30 within the controllable portion 28 may be actuated by a variety of methods. One method involves the use of electromechanical motors which may be individually mounted on each segment 30 to move the segments 30 relative to one another. Each segment 30 preferably defines at least one lumen running through it to provide an access channel through which wires, optical fibers, air and/or water channels, various endoscopic tools, or any variety of devices and wires may be routed through.

[0063] A more detailed description on the construction and operation of the segments may be found in U.S. Pat. Application Serial No. 09/969,927 entitled "Steerable Segmented Endoscope and Method of Insertion" filed October 2, 2001, which has been incorporated by reference in its entirety.

[0064] The guide 36 is generally used to impart a desired curvature initially defined by the steerable distal portion 24 and/or by the optional controllable portion 28 to the passive

proximal portion 22 when the endoscope 20 is advanced. If the guide 36 is advanced into the steerable distal portion 24, guide 36 is preferably advanced to or near the distal tip of the portion 24. The guide 36 may also be used partly to impart some column strength to the proximal portion 22 in order to maintain its shape and to prevent any buckling when axially loaded, such as when the endoscope 20 is advanced through a patient's colon. Construction of an endoscope 20 with the use of the guide 36 not only simplifies the control systems involved but it also represents a cost efficient device. Operation of the endoscope 20 with guide 36 will be discussed in detail below.

[0065] The guide 36 may be slidably disposed within the length of the endoscope body 21 and may freely slide entirely through the passive proximal portion 22, through the optional controllable portion 28, if utilized in the endoscope, and the steerable distal portion 24. Guide 36 may also be withdrawn through the instrument to any location within the body of endoscope 20. Moreover, guide 36 may be removed entirely from endoscope 20, if desired e.g., to accommodate additional working tools. In other words, there are preferably no constraints which may limit the travel of guide 36 within the body of endoscope 20.

[0066] Guide 36 may be advanced through proximal handle 32; alternatively, guide 36 may also be routed through a separate channel 37 dedicated to the guide 36. Channel 37 is may be attached to endoscope 20 near a proximal end of the instrument, such as a location off the proximal portion 22, and leads to a guide controller 41 which may be used to advance and/or withdraw guide 36 through endoscope 20. Guide controller 41 may also be used to selectively rigidize and relax guide 36 during use within a patient. Having guide controller 41 and proximal handle 32 separated may allow for the ease of use for the physician manipulating the endoscope 20. To aid in advancing guide 36 through endoscope 20, a pulley mechanism may be affixed within the steerable distal portion 24 through which a pull wire may extend over to connect the distal end of the guide 36 to a location outside the endoscope 20 for manipulation by the physician.

[0067] To facilitate the movement of guide 36 through endoscope body 21, a lubricious covering or coating may be applied over at least a majority of the length of guide 36 or onto the inner surface of the lumen through which guide 36 traverse, or both. Such coverings may include various polymers and plastics, e.g., PTFE, etc., which may simply cover the guide 36 length or which may be heatshrunk, coated, or bonded onto guide 36, depending upon the material used. The extent to which guide 36 traverses through the endoscope body 21 may be varied and adjusted according to the application.

[0068] Fig. 3A shows an isometric view of a length of the endoscope 20, in this example part of the proximal portion 22, with a section of the endoscope body 20 removed for clarity. As seen, a representative illustration of the guide 36 may be seen disposed within guide channel or lumen 50 within the proximal portion 22. Lumen 50 may be an existing working channel, i.e., an access channel for other tools, or it may be a designated channel for guide 36 depending upon the desired application. Guide 36 may be inserted within guide channel 50 through the endoscope handle 32 and pushed proximally through the remainder of the device, as seen in Fig. 2; or preferably, it may be pushed proximally or pulled distally, as necessary, through a separate guide controller 41, as discussed above. Although guide 36 is shown in this variation as being slidably disposed interiorly of endoscope body 20, it may also be disposed exteriorly of the body 20 to slide along a guide rail or exterior channel in other variations.

[0069] If guide 36 is located within a dedicated channel, such as lumen 50, the distal end of this channel is preferably closed or blocked at some distal location, e.g., within steerable distal portion 24 or within optional controllable portion 28, to prevent the influx of bodily fluids within lumen 50. Because an enclosed lumen 50 would further prevent contact of bodily fluids with guide 36, the amount of cleaning or sterilization of guide 36 is reduced.

[0070] If lumen 50 were left as an open channel, additional sterilization or cleaning and disinfection of guide 36 and lumen 50 may be necessary. Alternatively, lumen 50 may be left as an open channel but configured to have optional closing mechanisms, as shown in the examples of Figs. 3B and 3C, taken from Fig. 3A. Fig. 3B shows an end view of a trap or door 54 which is held within the body of the instrument and which may be rotated about a pivot 56 in the direction of the arrow to close access to lumen 50. Trap 54 may be closed during insertion of the instrument within a patient and then optionally opened to allow for working tools to be inserted therethrough. Fig. 3C shows another example where lumen 50 may be obstructed by an inflatable balloon 59 which may selectively expand to completely obstruct the passageway. Balloon 59 may be made of conventional materials and may be held within a compartment or step 58 such that lumen 50 is unobstructed when balloon 59 is deflated. These examples merely present variations and are not meant to limit the scope of the invention. Alternative designs and variations are intended to be within the scope of the present invention.

[0071] Figs. 4A to 4C show variations on possible cross-sections 4A-4A, 4B-4B, and 4C-4C, respectively, taken from Fig. 3A. Fig. 4A shows a simplified cross-section 22' of a guide 36 having a circular diameter slidably disposed within proximal portion 22. As seen,



guide 36 may be slidably positioned within channel 50', which may also be used as a working channel upon removal of guide 36 during, e.g., a colonoscopy procedure, for providing access for various instruments or tools to a treatment site. Fig. 4B shows another possible variation in cross-section 22'' where guide 36 is positioned within channel 50''. The variation of the proximal portion in cross-section 22'' may include a number of access lumens 52 optionally formed within the body of the device 20. These lumens 52 may run through the length of device 20 and may be used for various applications, e.g., illumination fibers, laparoscopic tools, etc. Although three lumens 52 are shown in the figure, any number of channels as practically possible may be utilized depending upon the application at hand. Fig. 4C shows another variation in cross-section 22''' . In this variation, guide 36' may be formed into a semi-circular or elliptical shape to slide within a similarly shaped channel 50''' . In this example, proximal portion 22''' also includes a working channel 52' which may be shaped accordingly to fit within the body 22''' along with channel 50''' to maintain a working channel without having to remove guide 36'.

[0072] In any of the above examples, the working or guide channels may be integral structures within the body of endoscope 20. Having an integral structure eliminates the need for a separate lumened structure, e.g., a separate sheath, through which guide 36 or any other tools may be inserted. Another variation utilizing multiple channels and multiple guides will be described in further detail below. These variations are not intended to be limiting but are merely presented as possible variations. Other structures and variations thereof may be recognized by one of skill in the art and are intended to be within the scope of the claims below.

[0073] The structure of the guide may be varied according to the desired application. The following description on the guide is presented as possible variations and are not intended to be limiting in their structure. Figs. 5A and 5B show cross-sectioned end and side views, respectively, of a guiding apparatus variation which is rigidizable by a vacuum force applied within the guide. It is preferable that the guide is selectively rigidizable, i.e., when the guide assumes a shape or curve in a flexible state, the guide may be rigidized to hold that shape or curve for a predetermined period of time. Although the endoscope structure of the present invention may utilize a guide which remains in a relatively flexible shape, it is preferable to have the guide be selectively rigidizable.

[0074] Guide 60 may be comprised of two coaxially positioned tubes, outer tube 62 and inner tube 64, which are separated by a gap 66 between the two tubes. Inner tube 64 may define an access lumen 68 throughout the length of the tube to provide a channel for

additional tools or other access devices. Both tubes 62, 64 are preferably flexible enough to be bent over a wide range of angles and may be made from a variety of materials such as polymers and plastics. They are also preferably flexible enough such that either the outer tube 62, inner tube 64, or both tubes are radially deformable. Once guide 60 has been placed and has assumed the desirable shape or curve, a vacuum force may be applied to draw out the air within gap 66. This vacuum force may radially deform inner tube 64 and bring it into contact with the inner surface of outer tube 62 if inner tube 64 is made to be relatively more flexible than outer tube 62. Alternatively, if outer tube 62 is made to be relatively more flexible than inner tube 64, outer tube 62 may be brought into contact with the outer surface of inner tube 64.

[0075] In another variation, tubes 62, 64 may both be made to be flexible such that they are drawn towards one another. In yet another variation, which may be less preferable, a positive force of air pressure or a liquid, e.g., water or saline, may be pumped into access lumen 68. The positive pressure from the gas or liquid may force the walls of inner tube 64 radially into contact with the inner surface of outer tube 62. In any of these variations, contact between the two tubular surfaces will lock the tubes 62, 64 together by frictional force and make them less flexible. An elastomeric outer covering 69, or similar material, may optionally be placed upon the outer surface of outer tube 62 to provide a lubricious surface to facilitate the movement of guide 60 within the endoscopic device. An example of a device similar to guide 60 is discussed in further detail in U.S. Patent No. 5,337,733, which has been incorporated herein by reference in its entirety.

[0076] Another variation on the guide is shown in Figs. 6A and 6B which show cross-sectioned end and side views, respectively, of a guiding apparatus variation 70 which is rigidizable by a tensioning member 76. Tensioned guide 70 is shown comprised of a series of individual segments 72 which are rotatably interlocked with one another in series. Each segment 72 may contact an adjoining segment 72 along a contacting lip 78. Each segment 72 may further define a channel therethrough which, collectively along with the other segments 72, form a common channel 74 throughout a majority of the length of guide 70. Segments 72 may be comprised of a variety of materials suitable for sustaining compression forces, e.g., stainless steel, thermoplastic polymers, plastics, etc.

[0077] Proximal and distal segments of guide 70 may hold respective ends of tensioning member 76, which is preferably disposed within common channel 74 through guide 70. Tensioning member 76 may be connected to a tensioning housing located externally of a patient. During use when the guide is advanced distally through an endoscope

of the present invention, tensioning member 76 is preferably slackened or loosened enough such that guide 70 is flexible enough to assume a shape or curve defined by the endoscope. When guide 70 is desirably situated and has assumed a desired shape, tensioning member 76 may be tensioned. This tightening or tensioning of member 76 will draw each segment 72 tightly against one another along each respective contacting lip 78 such that the guide 70 becomes rigid in assuming the desired shape. A lubricious covering, e.g., elastomers, etc., may be optionally placed over at least a majority of guide 70 to facilitate movement of the guide 70 relative to the endoscopic device. A similar concept and design is discussed in further detail in U.S. Patent No. 5,624,381, which has been incorporated herein by reference in its entirety.

[0078] Figs. 7A and 7B show cross-sectioned end and side views, respectively, of a guiding apparatus variation 80 which is rigidizable by a vacuum force which interlocks individual segments 82. Each segment 82 may be adjoined with adjacent segments by interlocking ball-and-socket type joints which are preferably gasketed at the interfaces 86 of each connection. Within each segment 82, with the exception of the distal segment, may be defined a channel which is narrowed at one end and flared at the opposite end. Collectively when the segments 82 are adjoined into the structure of guide 80, each of the individual channels form a common channel 84 which extends through at least a majority of the segments 82 along the length of guide 80. At the proximal end of guide 80 a vacuum pump, which is preferably located externally of the patient, is fluidly connected to common channel 84. In use, once guide 80 is manipulated in its flexible state within the endoscope to assume the desired shape or curve, ambient pressure may exist within common channel 84. When the rigid shape of guide 80 is desired, the pump may then be used to create a negative pressure within common channel 84 and this negative pressure draws each segment 82 into tight contact with one another to maintain the desired shape. When the vacuum force is released, each segment 82 would also be released and would thereby allow the guide 80 to be in its flexible state for advancement or withdrawal. Guide 80 may further be surrounded by an elastomeric or lubricious covering to aid in the advancement or withdrawal of the guide 80 within the endoscopic device.

[0079] Figs. 8A and 8B show cross-sectioned end and side views, respectively, of yet another guiding apparatus variation 90 which is optionally rigidizable by either a vacuum force or a tensioning member which interlocks individual segments 92. Segment 92 may be in the form of a segmented design with two opposed cups having a common channel 94 defined therethrough. Between each segment 92 are ball segments 96 which interfits along a

contact rim or area 97 within each adjacent segment 92. Ball segments 96 preferably contact adjacent cupped segments 96 within receiving channels 98 defined in each cup. When manipulated in its flexible state, guide 90 may be advanced or withdrawn or made to assume a desired shape or curve. When guide 90 is to be placed into its rigidized shape, a vacuum force or tensioning member 99 may be utilized in the guide 90 in similar manners as described above. Moreover, guide 90 may similarly be surrounded by an elastomeric or lubricious covering to aid in the advancement and withdrawal of the guide 90.

[0080] Figs. 9A and 9B show representative end and side views, respectively, of another guiding apparatus variation 100. This variation 100 comprises individual segments 102 having a uniform sleeve section 104 in combination with an integrated curved or hemispherical section 106. Each segment 102 is collinearly aligned with one another with the sleeve section 104 receiving the curved section 106 of an adjacent segment 102, as shown in Fig. 9C, which is the cross-section of guide 100 from Fig. 9B. The adjacent segments 102 may rotate relative to one another over the sleeve-hemisphere interface while maintaining a common channel 108 through the guide 100. A tensioning member 110 may pass through channel 108 along the length of guide 100 for compressing the individual segments 102 against one another when the entire guide 100 is rigidized.

[0081] Fig. 10 shows the cross-section of another variation 120 of the rigidizable guide apparatus. Representative segments are shown comprising spherical bead segments 122 alternating with sleeve segments 124. Each of the bead and sleeve segments 122, 124, respectively, may have a channel defined therethrough which allows for a tensioning member 126 to be run through the length of guide 120. The alternating segments allow for the rotation of the adjacent segments while the tensioning member 126 allows for the compression of the segments against one another when the guide 120 is to be rigidized in much the same manner as described above.

[0082] An alternative variation on the rigidizable guide is illustrated in Figs. 11A to 11C, which show a stiffening assembly having separate rigidizable coaxially positioned guides. Fig. 11A shows a representative number of nested segments 132 in nested stiffening assembly 130. Each nested segment 132 may be in a number of different configurations, e.g., ball socket joints, stacked ring-like segments, etc., with a tensioning member 134 passing through each of the segments 132. For use with nested assembly 130, an annular stiffening assembly 140 may be seen in Fig. 11B. Annular assembly 140, of which only a few representative segments are shown, are comprised in this variation of annular segments 142 which may be stacked or aligned one atop each other. At least one tensioning member 144,

and preferably at least two, may be passed through each of the annular segments 142. A central area 146 is defined in each annular segment 142 such that nested stiffening assembly 130 may be slidably placed within the central area 146 defined by the annular stiffening assembly 140. Fig. 11C shows the stiffening assembly 130 slidably positioned within annular stiffening assembly 140 to form the coaxially aligned stiffening assembly 150. Use of coaxial assembly 150 will be described in further detail below.

[0083] In operation, any of the guiding apparatus as described above or one recognized by a person of skill in the art to be suitable for such use as described herein may be utilized. Figs. 12A to 12H illustrate a representative method of advancing a colonoscopic device 20 as described herein with a representative guide 36 for advancement into a patient's colon C. As seen in Fig. 12A, the steerable distal portion 24 of colonoscope 20 may be first advanced into the patient's rectum via anus A. The device 20 may be simply advanced, either manually or automatically by a motor, until the first curvature is reached or alternatively until the segments of controllable portion 28 are within colon C. At this point, the steerable distal portion 24 may be actively controlled by the physician or surgeon to attain an optimal curvature or shape for advancement of device 20. The optimal curvature or shape is considered to be the path which presents the least amount of contact or interference from the walls of colon C. If the optional controllable portion 28 is used with the colonoscopic device 20, once the advancement position 160 has been determined, the device 20 may be advanced further into the sigmoid colon S such that the automatically controlled segments of controllable portion 28 follow the distal portion 24 while transmitting the optimal curvature or shape proximally down the remaining segments of controllable portion 28.

[0084] Alternatively, once steerable distal portion 24 has been steered or positioned for advancement 160, guide 36 may be advanced distally in its flexible state along or within device 20 until it reaches a distal position, i.e., some point distal of the flexible proximal portion 22 and preferably to the distal end of the device 20, as shown in Fig. 12B. Preferably, guide 36 is advanced to the distal end of steerable distal portion 24 or to the distal end of the optional controllable portion 28, if utilized, or to some point therebetween. Guide 36 may be advanced to any distal position as long as a portion of guide 36 attains the optimal curvature or shape. Prior to advancing the device 20 over guide 36, the guide 36 may be left in its flexible state or it may be optionally rigidized, as discussed above. If left in its flexible state, guide 36 will still provide desirable column strength to the device 20 as it is advanced through colon C over the guide 36. It is preferable, however, that guide 36 is rigidized once it has attained and conformed to the curvature. As the position of guide 36 is preferably rigidized

and maintained, the device 20 may then be advanced over or along the guide 20 in a monorail or "piggy-back" fashion so that the flexible proximal portion 22 follows the curve held by guide 36 until the device 20 reaches the next point of curvature. The following description discusses the use of the optional controllable portion 28; however, this portion 28 may be omitted from the device 20.

[0085] As shown from Fig. 12B to 12C, the curve is maintained by guide 36 until the steerable distal portion 24 has been advanced to the juncture between the sigmoid colon S and the descending colon D. At this point, the distal portion 24 may be actively steered by the physician using a variety of visualization techniques, e.g., steering via an optional imaging bundle 40 located at the distal end of the device 20. Once the optimal curve or shape has been determined, the device 20 may be advanced to position 160. As the device is moved distally, if the controllable portion 28 is utilized, portion 28 will automatically follow the path set by the distal portion while the flexible proximal portion follows the device 20 along the curvature defined by the guide 36. Otherwise, if controllable portion 28 is omitted, guide 36 will have its curvature defined solely by steerable distal portion 24. Once the junction between the sigmoid colon S and descending colon D has been traversed by the steerable distal portion 24 and the optional controllable portion 28, the guide may then be relaxed and advanced distally along the device 20 in its flexible state until it reaches the distal position in the device 20. As the guide 36 is advanced, it will attain and conform to a new curvature defined by the steerable distal portion 24 and/or the controllable portion 28, as shown in Fig. 12D.

[0086] Having attained a new curvature, guide 36 may again be rigidized to maintain this shape. While the guide 36 maintains this shape, the device 20 may be advanced further distally along the descending colon D with the help of the rigidized guide 36 in the piggy-back manner described above to define the path for the flexible proximal portion 22 and to prevent excessive contact with the walls of colon C. As shown in Fig. 12E, the device 20 has been advanced past the left (splenic) flexure F<sub>1</sub> in the manner described above until the optional controllable portion 28 has attained the optimal curvature. The guide 36 may be relaxed again and advanced further distally in its flexible state, as shown from Figs. 12E to 12F.

[0087] After guide 36 has assumed the desired curvature defined by the distal portion 24 and/or controllable portion 28, as shown in Fig. 12F, it may again be rigidized and the device 20 may then be advanced through the transverse colon T and around the right (hepatic) flexure F<sub>2</sub> in much the same manner as described above and as shown in Fig. 12G. Once the distal portion 24 and the optional controllable portion 28 has controllably negotiated past the

right (hepatic) flexure F, the position of guide 20 may again be maintained while guide 36 is relaxed once again and advanced distally to assume the new curvature defined by distal portion 24 and/or controllable portion 28, as shown in Fig. 12H. After guide 36 is optionally rigidized again, device 20 may be advanced completely within the ascending colon G towards the cecum E for a complete examination of the colon C with minimal complication and effort.

[0088] While the device 20 is advanced through the colon C, the physician or surgeon may stop the advancement to examine various areas along the colon wall using, e.g., the imaging bundle 40. During such examinations, the guide 36 may be temporarily withdrawn manually or automatically from the device 20 to allow for the insertion of other tools through the guide channel 50. After a procedure has been completed on the colon wall, the tool may be withdrawn from guide channel 50 and guide 36 may be reintroduced into the device 20 so that the device may optionally be advanced once again into colon C.

[0089] To withdraw device 20 from within the colon C, the procedure above may be reversed, as shown in Fig. 13A, such that the withdrawal 162 minimally contacts the walls of colon C. Alternatively, guide 36 may simply be removed from device 20, as shown in Fig. 13B, while leaving device 20 within colon C. The device 20 may simply be withdrawn by pulling the proximal portion 22 to remove the device 20. This method may rub or contact the device 20 upon the walls of colon C, but any impingement would be minimal.

[0090] An alternative method of advancing an endoscope through a tortuous path may be seen in Figs. 14A to 14C by using the rigidizable guide assembly 150 seen from Fig. 11C. Fig. 14A shows a pathway to be negotiated by endoscopic device 172. The pathway may represent a portion of colon 170. As device 172 is desirably steered to assume a curve, nested stiffening assembly 130 may be advanced distally within device 172 to distal end 174 while in a relaxed state. Alternatively, nested assembly 130 may be advanced in the flexible, relaxed state along with the distal end 174.

[0091] Once the curve has been selected, nested assembly 130 may be stiffened to maintain its shape. At this point, annular stiffening assembly 140 may be advanced over nested assembly 130 towards distal end 174. Once assembly 140 has assumed the curve defined by assembly 130, annular assembly 140 may then be rigidized and nested assembly 130 may be relaxed into its flexible state, as shown in Fig. 14B. Then the distal end 174 may be further advanced with or without assembly 130 while being pushed along the curve defined by rigidized annular assembly 140, as shown in Fig. 14C. Once distal end 174 of device 172 has negotiated the curve, nested assembly 130, after being advanced to distal end 174, may

then be rigidized again and annular assembly 140 may be relaxed and advanced again over assembly 130 and so on until the desired treatment location has been reached within the body.

[0092] Another alternative variation on advancing an endoscope through a tortuous path may be seen in Figs. 15A to 15E. This variation uses multiple guides which may be alternately rigidized while being advanced distally along the path. Fig. 15A shows a portion of the curved pathway in colon 170 with endoscope 180 being advanced therethrough. Multiple guides may be used in this variation, but preferably two guides are utilized, as described below. Any one of the rigidizable guide variations discussed herein may be used solely or in combination with different types of guides in the same device 180. Each guide may be advanced within its own lumen defined within the endoscope, or they may also share a common dedicated lumen.

[0093] As device 180 approaches a curvature of colon 170, first guide 184 may be advanced towards the steerable distal end 182. While being advanced, first guide 184 is in a relaxed and flexible state allowing it to conform to the shape defined by the distal end 182. Having been advanced to distal end 182, as shown in Fig. 15B, first guide 184 is rigidized to maintain the shape defined by the steerable distal end 182. Device 180 may then be advanced further distally into colon 170 while riding over rigidized first guide 184.

[0094] After device 180 has been further advanced to a new position, second guide 186 may also be advanced distally in its relaxed state through device 180 up to the distal end 182 while first guide 184 is preferably still rigidized, as shown in Fig. 15C. As second guide 186 advances, it may conform to a new shape defined by device 180. Second guide 186 may then be rigidized to hold its shape. First guide 184 may be relaxed but its rigid shape is preferably also maintained while the distal end 182 of device 180 is further advanced distally through colon 170, as shown in Fig. 15D.

[0095] After device 180 has been advanced distally, first guide 184 may be relaxed and advanced through device 180 up to distal end 182 while the rigidity of second guide 186 is maintained, as shown in Fig. 15E. Second guide 186 may be relaxed and then advanced in its flexible state distally through device 180 and so on. This process may be repeated as device 180 is required to negotiate arbitrarily tortuous paths.

[0096] In an alternative variation of the present invention, guide 202 and endoscope 204 are slidably interlocked adjacent to one another, as shown in Fig. 16A. Slidably interlocking the guide and endoscope adjacent to one another, in contrast with the guide being positioned within the lumen of the endoscope, allows the working lumen of the endoscope to remain free. Thus, other devices, fluids, or drugs for delivery may be transported or delivered



through the lumens of the endoscope. Slidably interlocking the guide and endoscope adjacent to one another also affords greater control over the endoscope and guide from a position external to a patient's body and allows for their uncomplicated movement relative to one another. This variation further reduces the risk that contaminants will get inside the endoscope, since the lumen may remain closed when no access is needed therethrough. This variation also eliminates the need to advance the guide through the lumen of the endoscope, which is accessible for insertion typically through its proximal end. Instead, the guide and endoscope may be interlocked at any desired location outside the patient's body. Consequently, the length of the guide necessary to carry out an examination or other procedure is reduced. Any number of methods may be used to slidably interlock the guide and endoscope.

[0097] In one variation, an interlocking device 200 is used to receive and slidably interlock guide 202 with endoscope 204, as shown in Fig. 16B. In this variation, the guide and endoscope are inserted into the interlocking device and interlocked prior to advancing guide 202 or endoscope 204 distally into a patient's body cavity in the monorail type fashion described above. Because the guide and endoscope are slidably interlocked, their movement relative to one another may be independently controlled. That is, while adjacently interlocked with the endoscope, guide 202 may first be advanced distally. Endoscope 204 may be advanced distally thereafter.

[0098] Interlocking device 200 has a proximal end 206, a distal end 208, and a lumen 210 therethrough. As shown in Fig. 16C, interlocking device 200 may also have a segregating member 212 disposed within lumen 210 for defining separate compartments for receiving the endoscope and guide therein. The segregating member can be positioned vertically or horizontally or have any number of configurations, provided that it helps define separate spaces for the insertion of the guide and endoscope within the interlocking device. A few such configurations are provided in Fig. 16C. Alternatively, interlocking device 200 may have no segregating member.

[0099] Interlocking device 200 may be integrated into a single unit with axial motion transducer 49, described above, or it may be a stand-alone unit positioned proximally, distally, or adjacent to transducer 49 (depending on the desired configuration). The interlocking device may also be affixed to a table upon which the patient lies, or alternatively, may be free to slide along the length of guide 202 or endoscope 204 to accommodate their relative movement. As illustrated in Fig. 16D, guide 202 and endoscope 204 are advanced distally

into proximal end 206 of interlocking device 200. Interlocking device 200 receives and slidably interlocks endoscope 204 and guide 202 adjacent to one another.

[0100] In one variation, shown in Fig. 16E, interlocking device 200 slidably interlocks guide 202 and endoscope 204 by providing pressure sufficient to releasably secure guide 202 within a channel 214 positioned along the outer surface of endoscope 204 (e.g., much like a pressure lock zipper). This may be accomplished in any number of ways. For example, interlocking device 200 may be constructed of a rigid material and have a lumen diameter, D1, less than the combined diameter of the guide and endoscope when not interlocked, D2. In this way, the interlocking device cannot accommodate the guide and endoscope if not interlocked. Therefore, when guide 202 and endoscope 204 are inserted within its lumen, they are forced together until their outer surfaces fit therein. Manual pressure may instead be applied to the outer surface of interlocking device 200 for compressing guide 202 into channel 214 positioned along the outer surface of endoscope 204. Alternatively, pressure may be applied to the outer surface of interlocking device 200 automatically and be controlled remotely by a processor.

[0101] Any number of channel configurations may be used with interlocking device 200. A few such configurations are illustrated in Figs. 17A-H. For example, in one variation, the guide is adapted to fit within channel 214 positioned along the outer surface of endoscope 204 as shown in Fig. 17A. The endoscope and channel may be combined within a single structure or housing or the two may be separate components. In either case, the endoscope having the channel may first be inserted into the proximal end of the interlocking device. The guide may then be inserted into the proximal end of the interlocking device and pressure applied. As described above, when the interlocking device is configured such that there is a snug fit between the lumen wall of the interlocking device and the combined guide and endoscope, no additional pressure may be necessary. In another variation, the endoscope is adapted to fit within channel 214 located along the outer surface of guide 202 as shown by Fig. 17B.

[0102] Channel 214 need not be continuous along the outer length of the endoscope or guide. It may for example be attached only to a portion thereof. The channel may also be slidable to allow its movement along the outer length of either the endoscope or the guide. In this way, the channel can be positioned at any desired location along the guide or endoscope and be advanced to the proximal end of the interlocking device with ease. Having a discontinuous channel also eliminates the need to prefabricate an endoscope or guide having a channel configured thereon. As will be described in more detail below, the channel may be

manufactured separately and then attached to the endoscope or guide using any number of methods.

[0103] In one variation, the channel is comprised of a series of semi-circular shaped rings 216 as illustrated by Fig. 17C. In this variation, the channel comprises two portions. A first portion 218 is attached to the guide or endoscope, and a second portion 220 is configured to receive the endoscope or guide within its semicircular shaped structure. For example, as shown in Fig. 17D, first portion 218 may completely surround the endoscope or guide, or may itself be comprised of semi-circular shaped rings. Similarly, the first portion 218 may be slidable along the length of the endoscope or the guide, be removable therefrom, or be permanently affixed thereto. Second portion 220 is integral to first portion 218, and as illustrated in Fig. 17D, has a semi-circular shaped structure and is configured to receive a endoscope or guide therein. Any number of these semi-circular shaped channels may be used.

[0104] The channel accommodating the guide or endoscope may further be partially open or be completely closed. If the channel is closed, then the guide or endoscope may need to be advanced into the channel through its proximal end. If the channel is discontinuous, this can occur immediately proximal to the interlocking device. However, if the channel is continuous along the entire length of the endoscope or guide, it could contain an entry slit 222 along its surface to allow for insertion of the corresponding device, as shown in Fig. 17E. The slit may be opened proximal to the interlocking device for insertion therein. Similarly, interlocking device 200 may have a slit 224 along its surface to allow insertion and withdrawal of the guide or endoscope within the closed channel, as shown in Fig. 17F.

[0105] In another variation, the endoscope or guide has a projecting member and the corresponding guide or endoscope has a locking member for receiving the projecting member therein. For example, as illustrated in Fig. 17G, projecting member 226 is positioned along the outer surface of the endoscope 204 and is adapted to fit within corresponding locking member 228 located along the outer surface of guide 202. The projecting member may be disposed along the entire length of the guide or endoscope, or only a portion thereof. Similarly, the projecting member may be movable along the outer surface of the endoscope or guide to allow it to be positioned immediately proximal to the point of entry for the guide and endoscope into the locking device. The guide or endoscope having the projecting member is then first inserted into interlocking device 200 through its proximal end 206. The guide or endoscope having the locking member is then inserted into proximal end 206 of interlocking device 200. As the guide and endoscope are pushed forward distally into interlocking member 200, they become slidably interlocked as the locking member 228 engages projecting member

226. As described above, this may or may not require the application of external pressure to the interlocking device 200.

[0106] Another alternative may utilize magnets placed along either the endoscope or guide, or both. Such magnets may be continuous along the instrument or they may be discrete magnets placed intermittently along the instrument. The magnets interlock the endoscope and guide by providing sufficient holding force to retain the guide or endoscope in a channel positioned along the outer surface of the corresponding endoscope or guide. Fig. 17 H provides an illustration of one variation of the present invention wherein magnets are used. As shown therein, magnets 236 may be used to interlock endoscope 204 and the guide (not shown). The magnets may be placed at any position along the length of the endoscope, guide, or their corresponding channels. Similarly, the magnets may be of any number and take on any number of configurations. For example, magnets 236 may be positioned within the partially open channel 214 (as shown in Fig. 17H) or may instead be positioned on the outer surface of the guide. Making reference now to Fig. 17H, the magnets interlock endoscope 204 and the guide by providing sufficient holding force to retain the guide in channel 214, which is positioned along the outer surface of the corresponding endoscope. However, in another variation, channel 214 may be positioned along the outer surface of the guide and the endoscope may be retained therein by magnets 236, which provide sufficient holding force. Optionally, an interlocking device may be used to further align and join the endoscope and guide.

[0107] In another variation, multiple channels along the outer surface of endoscope or guide are provided. These channels may be used for the insertion of multiple guides or additional tools and devices. These channels may be any number of sizes to accommodate the varying circumferences of the various guides, tools, or devices. The channels may also be slidable, removable, or affixed to the outer surface of the guide or endoscope as described above. They may further be continuous or discontinuous along the length of endoscope or guide.

[0108] While there are no actual limitations on the type of geometry or material that may comprise the various channels described herein, the geometry and material should be suitable for its intended purpose. For example, for use of the present invention with the colonoscopy procedures described above, the channel should easily accommodate the shape of the endoscope or guide and be made of a flexible material. This allows for the seamless interlocking of the endoscope and guide by the interlocking device and also allows for flexing

and bending of the channel during an examination or other procedure. In either case, the channel may be made of a material that is also biocompatible, e.g., thermoplastic polymers.

[0109] The channels may be made using any number of materials and may be attached to the endoscope or guide using any number of methods. For example, the channel may be fabricated using the same material as the endoscope or guide covering and may even comprise a portion thereof. In this way, the channel may be made using a thermal forming process in which the channel is shaped after the guide or endoscope has been formed via a heating process. In other variations, the guide or endoscope may not have a channel integrally affixed thereto, and the channel is instead attached to the guide or endoscope. In these variations, the channel can be attached to the endoscope or guide using any number of methods. For example, the channel may be attached using adhesives (e.g., bonding formulas, resins, glues, cements, etc.) or mechanical fasteners (e.g., clamps, magnets, etc.). The channel may also be attached to the guide or endoscope by crimping it onto the outer surface of the guide or endoscope. In situations where it is advantageous to have a movable channel, a channel may be provided that snap fits onto the outer surface of the guide or endoscope without requiring it be further secured. In this way, the channel will be movable along the length of the guide or endoscope and to a site just proximal to the lumen of the interlocking device.

[0110] Fig. 18 illustrates how the interlocking device described herein may be used to advance a colonoscopic device into a patient's colon C. As shown by Fig. 18, colonoscope 230 and guide 202 are first advanced into interlocking device 200, which is located a close distance, six inches for example, from the point of insertion of colonoscope 230 and guide 202 into the patient's colon C. The interlocking device then slidably interlocks guide 202 and colonoscope 230 by any of the methods described above.

[0111] Dispenser 232 may be used to house guide 202 and release it in any given quantity. Dispenser 232 may additionally serve to house various tensioning elements, so that guide 202 may be selectively rigidized as described above. Once interlocked, the guide and colonoscope can then be advanced manually, or automatically (using processor 234) into the patient's colon C using any number of the advancement methods set forth in detail above.

[0112] In another variation, the guide and endoscope are adjacently interlocked without the use of an interlocking device. In this variation, an interlocking channel may be provided along the outer surface of the endoscope or guide to releasably secure the guide and endoscope while allowing them to slide relative to one another.

[0113] Although the endoscope of the present invention has been described for use as a colonoscope, the endoscope can be configured for a number of other medical and industrial

applications. In addition, the present invention can also be configured as a catheter, cannula, surgical instrument or introducer sheath that uses the principles of the invention for navigating through tortuous body channels. The present invention may also be used for industrial applications such as inspection and exploratory applications within tortuous regions, e.g., machinery, pipes, etc.

[0114] In a variation of the method that is particularly applicable to laparoscopy or thoracoscopy procedures, the steerable endoscope can be selectively maneuvered along a desired path around and between organs in a patient's body cavity. The distal end of the endoscope may be inserted into the patient's body cavity through a natural opening, through a surgical incision or through a surgical cannula, introducer, or trocar. The selectively steerable distal portion can be used to explore and examine the patient's body cavity and to select a path around and between the patient's organs. The electronic motion controller in conjunction with the tracking rod can be used to control the automatically controlled proximal portion to follow the selected path and allow the rest of the body to follow the tracking rod and, if necessary, to return to a desired location using the three-dimensional model in the electronic memory of the electronic motion controller. Modification of the above-described assemblies and methods for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims.

## CLAIMS

We claim:

1. A method of advancing an instrument along an arbitrary path using a guiding apparatus adjacently positioned to the instrument, comprising:
  - selectively steering a distal portion of the instrument to assume a selected shape along an arbitrary path;
  - advancing an elongate guide adjacent to the instrument such that a portion of the guide conforms to and assumes the selected shape; and
  - maintaining a position of the guide while advancing the instrument adjacent to the guide such that a proximal portion of the instrument assumes the selected shape defined by the guide, wherein the elongate guide is freely slidable along the instrument such that advancing of the instrument along the guide is unconstrained.
2. The method of claim 1 further comprising advancing the instrument distally while configuring a controllable portion of the instrument to assume the selected shape of the distal portion prior to advancing the elongate guide adjacent to the instrument, wherein the controllable portion is proximal of the distal portion.
3. The method of claim 1 further comprising measuring a depth change of the instrument while advancing the instrument distally.
4. The method of claim 3 further comprising incrementing a current depth by the depth change.
5. The method of claim 1 further comprising releasing the position of the guide and further advancing the guide adjacent to the instrument.
6. The method of claim 1 further comprising withdrawing the guide adjacent to the instrument.
7. The method of claim 1 wherein the distal portion of the instrument selectively assumes a second shape when the instrument is advanced adjacent to the guide.

8. The method of claim 7 further comprising advancing at least one additional elongate guide adjacent to the instrument such that the additional elongate guide conforms to and assumes the second shape.
9. The method of claim 8 further comprising rigidizing the additional elongate guide such that the second shape is maintained by the additional guide.
10. The method of claim 1 wherein maintaining the position of the guide comprises rigidizing the guide such that the guide rigidly assumes a position of the selected shape.
11. The method of claim 10 wherein rigidizing the guide comprises applying tension to a tensioning member disposed within the guide such that a plurality of adjacent segments comprising the guide are compressed.
12. The method of claim 10 wherein rigidizing the guide comprises applying a vacuum force within a lumen defined within the guide such that a plurality of adjacent segments comprising the guide are compressed.
13. The method of claim 1 wherein prior to advancing the elongate guide, the elongate guide is first advanced into an interlocking device where it becomes slidably interlocked with the instrument.
14. The method of claim 13 wherein the interlocking device compresses the elongate guide into a channel positioned on the outer surface of the instrument.
15. The method of claim 13 wherein the interlocking device compresses the instrument into a channel positioned on the outer surface of the elongate guide.
16. The method of claim 13 wherein the interlocking device facilitates magnetic attachment of the elongate guide within a channel on the outer surface of the instrument.
17. The method of claim 13 wherein the interlocking device facilitates magnetic attachment of the instrument within a channel on the outer surface of the elongate guide.



18. The method of any of claims 14, 15, 16, or 17 wherein the channel is partially open.
19. The method of either claim 14, 15, 16, or 17 wherein the channel is non-continuous.
20. An apparatus for insertion into a body cavity, comprising:  
an elongate body having a proximal portion and a selectively steerable distal portion and defining a lumen therebetween, the steerable distal portion being configurable to assume a selected shape along an arbitrary path;  
an elongate guide having a proximal section, a distal section, and a length therebetween, the guide being slidably disposed without constraint adjacent to the elongate body for selectively supporting the body, wherein the guide is configured to conform to and selectively maintain the selected shape assumed by the steerable distal portion, and wherein the proximal portion of the elongate body when advanced distally is configured to conform to the selected curve maintained by the guide.
21. The apparatus of claim 20 further comprising a controllable portion located proximally of the distal portion, wherein the controllable portion is configured to propagate the selected shape along the controllable portion.
22. The apparatus of claim 20 wherein the selectively steerable distal portion is configurable via a control located externally of the body cavity.
23. The apparatus of claim 20 wherein the proximal portion comprises a flexible tubular member.
24. The apparatus of claim 21 wherein the controllable portion comprises a plurality of pivotally connected segments.
25. The apparatus of claim 24 wherein each of the segments comprises an actuator for propagating the selected shape along the controllable portion.

26. The apparatus of claim 25 wherein the actuator comprises a type of motor selected from the group consisting of pneumatic, hydraulic, electromechanical motors, and drive shafts.
27. The apparatus of claim 24 wherein the controllable portion comprises at least two pivotally connected segments.
28. The apparatus of claim 20 wherein the elongate guide is configured to assume the selected shape when the guide is in a flexible state and wherein the guide is further configured to maintain the selected shape when the guide is in a rigidized state.
29. The apparatus of claim 28 wherein the elongate guide is configured to selectively rigidize along the external length of the guide to maintain the selected shape in the rigidized state.
30. The apparatus of claim 28 wherein the proximal section of the elongate guide is in communication with a guide controller for selectively rigidizing the guide along its length.
31. The apparatus of claim 28 wherein the elongate guide comprises a plurality of adjacent segments each defining a channel therethrough such that a common channel is defined through the length of the guide.
32. The apparatus of claim 31 further comprising a tensioning member disposed within the common channel such that applying a force to the tensioning member compresses the adjacent segments together.
33. The apparatus of claim 31 wherein the elongate guide is configured to maintain a position of adjacent segments relative to each other upon applying a vacuum force within the common channel.
34. The apparatus of claim 20 further comprising an obstruction located within the lumen distally of the guide for preventing contamination of the guide.

35. The apparatus of claim 34 wherein the obstruction is selectively removable from a passageway of the lumen.

36. The apparatus of claim 35 wherein the obstruction comprises a trap or an expandable balloon.

37. The apparatus of claim 20 further comprising at least one additional elongate guide having a proximal section, a distal section, and a length therebetween, the additional guide also being slidably disposed adjacent to the elongate body and being configured to conform to and selectively maintain an additional selected curve assumed by the steerable distal portion.

38. The apparatus of claim 20 further comprising a tubular covering disposed over at least a majority of the length of the elongate guide.

39. The apparatus of claim 20 further comprising an interlocking device for receiving and slidably interlocking the elongate body and elongate guide.

40. The apparatus of claim 39 wherein the elongate guide has a channel positioned on at least a portion of its outer surface.

41. The apparatus of claim 40 wherein the channel has at least one magnetic portion on at least a portion of its inner surface.

42. The apparatus of claim 40 wherein the elongate body has at least one magnetic surface positioned on at least a portion of its outer surface.

43. The apparatus of claim 39 wherein the elongate body has a channel positioned on at least a portion of its outer surface.

44. The apparatus of claim 43 wherein the channel has at least one magnetic portion on at least a portion of its inner surface.

45. The apparatus of claim 43 wherein the elongate guide has at least one magnetic surface positioned on at least a portion of its outer surface.
46. The apparatus of either claim 40 or 43 wherein the channel is closed, the closed channel having an entry slit disposed along its length.
47. The apparatus of either claim 40 or 43 wherein the channel is at least partially open.
48. A device for slidably interlocking an elongate body and an elongate guide adjacent to one another comprising:  
a proximal end, a distal end, and a lumen therethrough, the lumen configured to receive an elongate body and an elongate guide therein; and  
a mechanism configured to provide pressure sufficient to slidably interlock the elongate guide and elongate body to one another while advancing the elongate guide and elongate body through the lumen.
49. The device of claim 48 further comprising a segregating member disposed within the lumen for defining separate compartments in which the elongate body and elongate guide are to be received.
50. The device of claim 48 wherein the mechanism configured to provide pressure comprises a lumen diameter that is less than the combined diameter of the elongate guide and elongate body when not interlocked.
51. The device of claim 48 wherein the mechanism to provide pressure further comprises a processor for controllably applying pressure to the outer surface of the device.
52. A method for slidably interlocking an elongate body and an elongate guide adjacent to one another comprising the steps of:  
providing an interlocking device having a proximal end, a distal end, and a lumen therethrough;  
advancing an elongate body into the lumen of the interlocking device; and  
advancing an elongate guide into the lumen of the interlocking device.

53. The method of claim 52 further comprising the step of applying pressure to the outer surface of the interlocking device.

54. The method of claim 52 wherein the elongate body has a channel positioned on at least a portion of its outer surface.

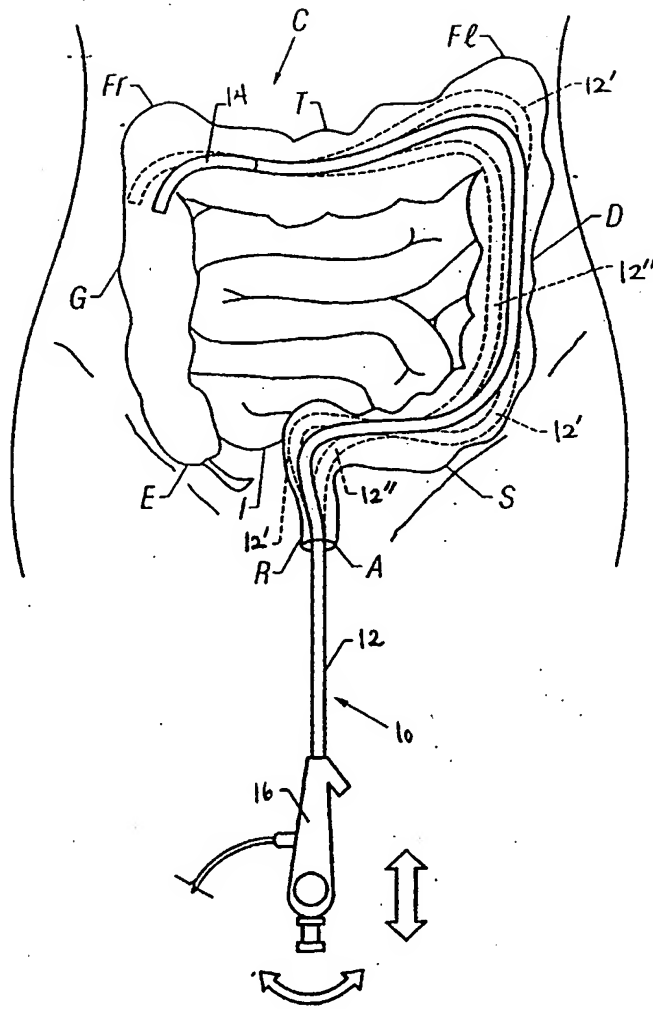
55. The method of claim 52 wherein the elongate guide has a channel positioned on at least a portion of its outer surface.

56. The method of either claim 54 or 55 wherein the channel is slidable.

57. The method of either claim 54 or 55 wherein the channel is permanently affixed to the outer surface.

58. The method of claim 52 wherein the elongate guide is advanced into the lumen of the interlocking device at its proximal end.

59. The method of claim 52 wherein the elongate body is advanced into the lumen of the interlocking device at its proximal end.



**FIG. 1**  
**(Prior Art)**

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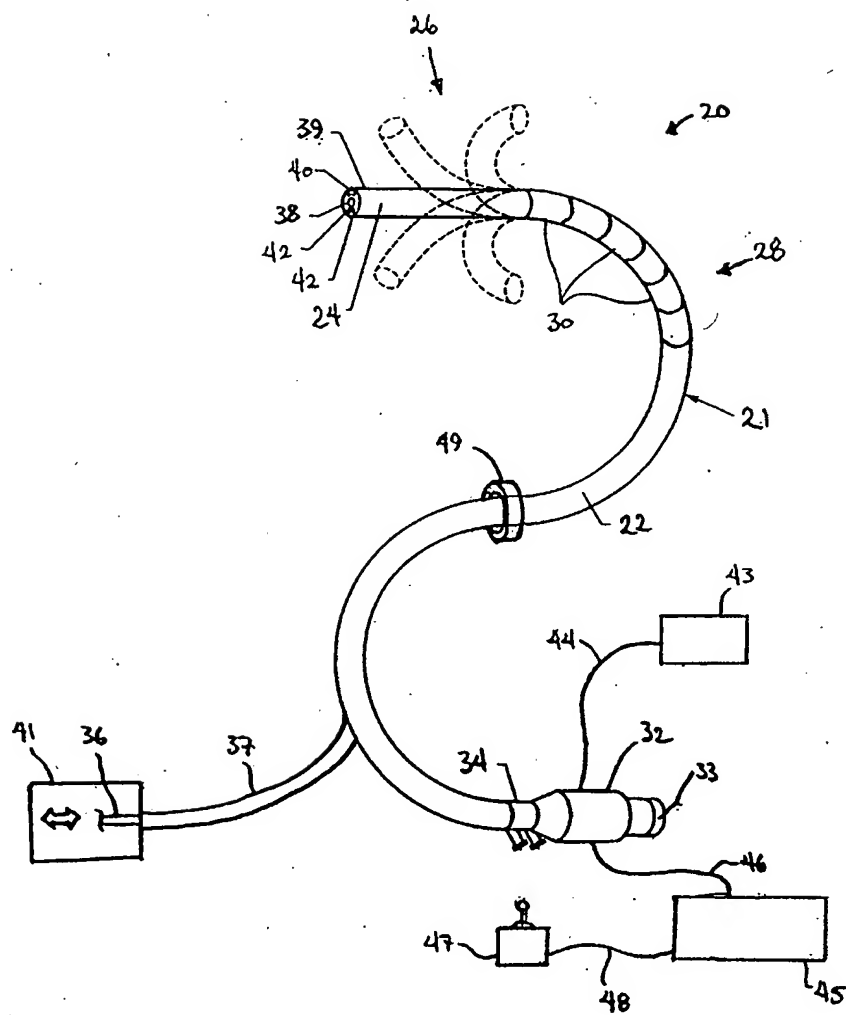
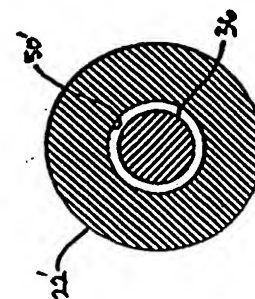
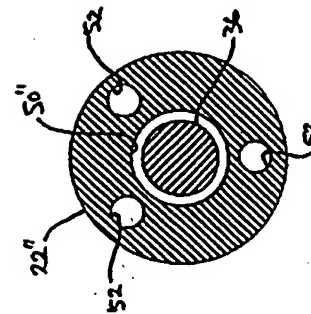
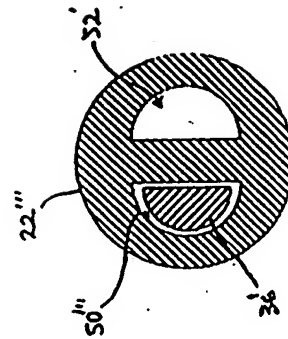
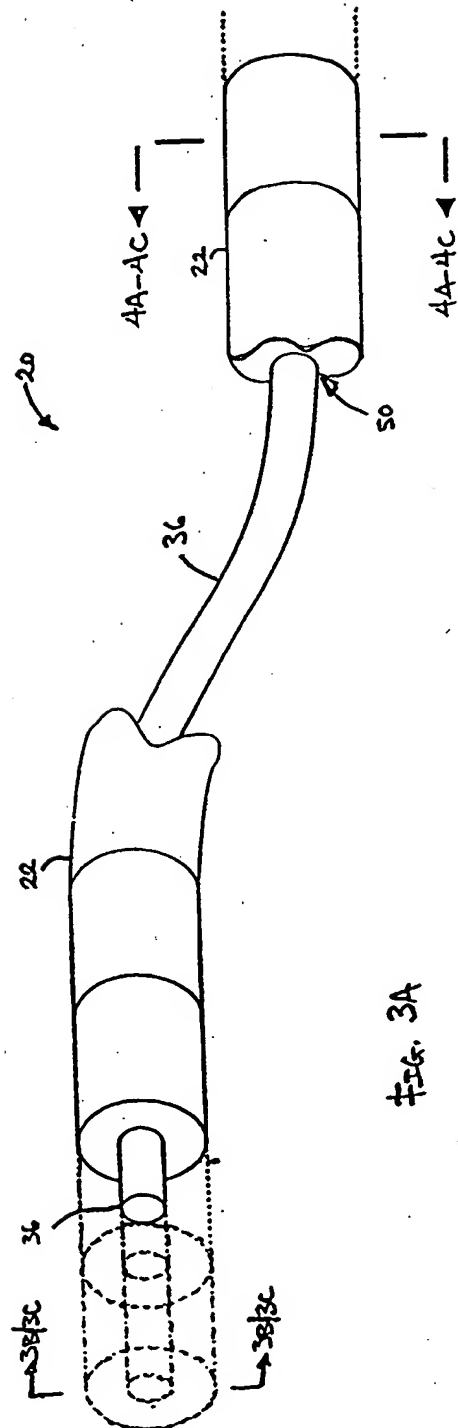


FIG. 2

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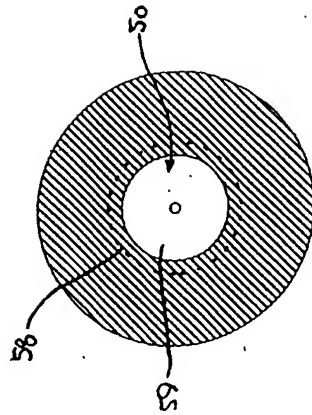


FIG. 3C

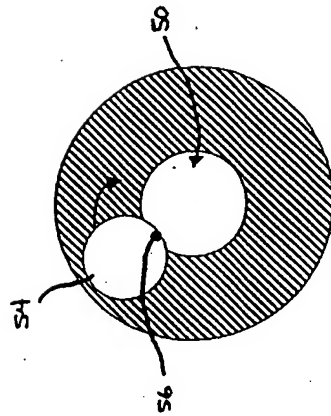


FIG. 3B

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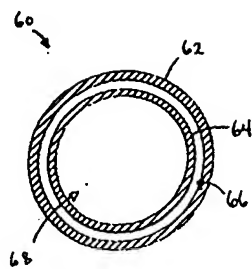


FIG. 5A

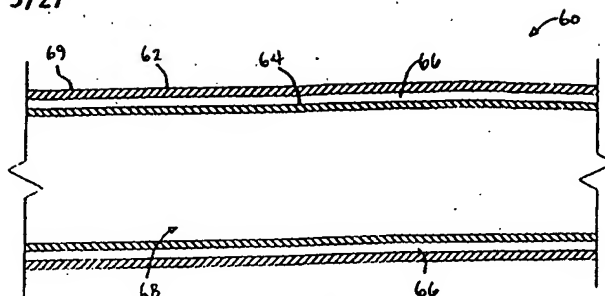


FIG. 5B

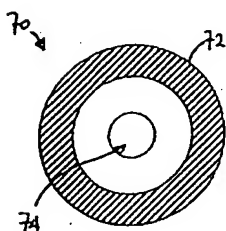


FIG. 6A

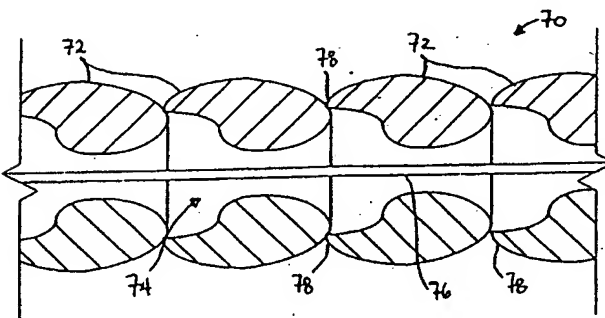


FIG. 6B

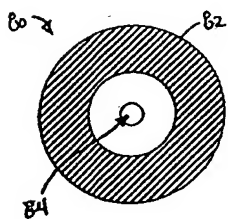


FIG. 7A

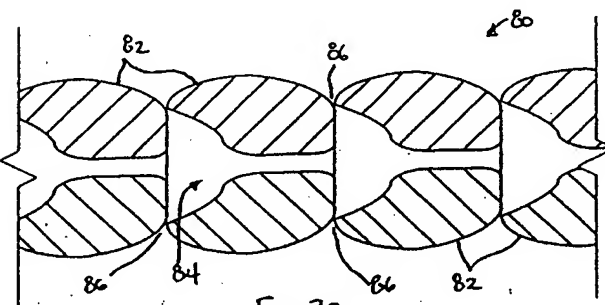


FIG. 7B

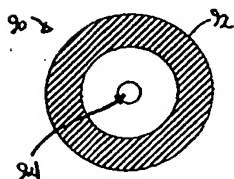


FIG. 8A

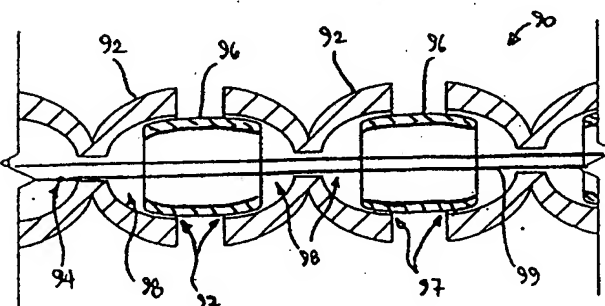


FIG. 8B

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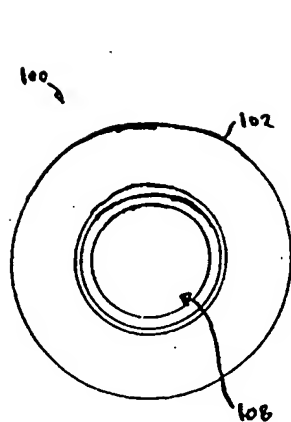


FIG. 9A

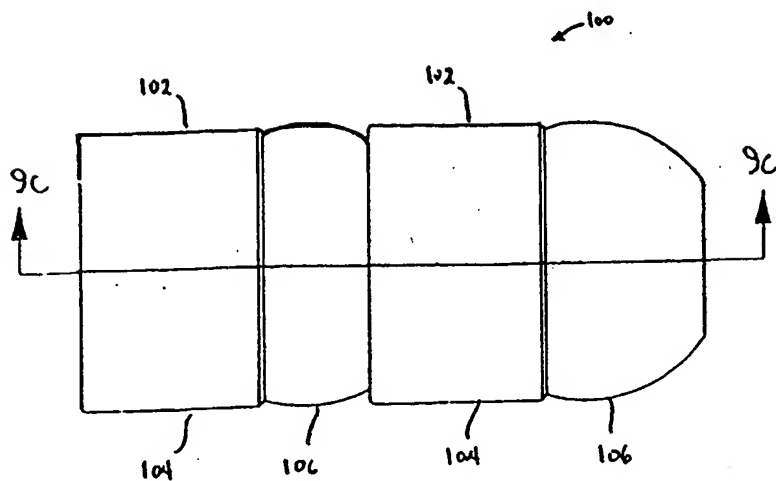


FIG. 9B

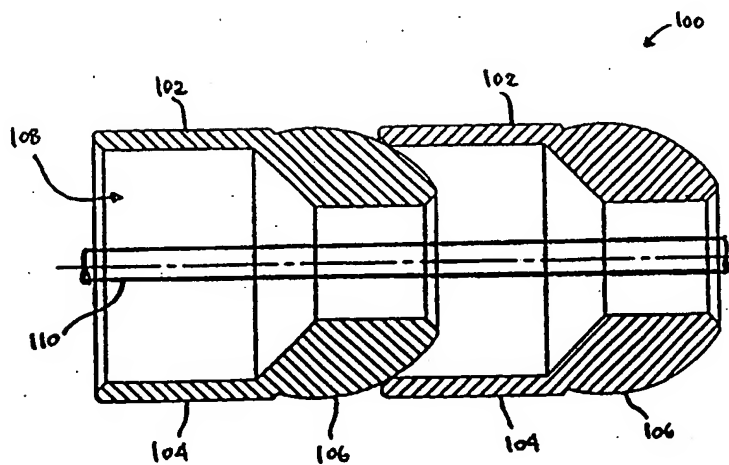


FIG. 9C

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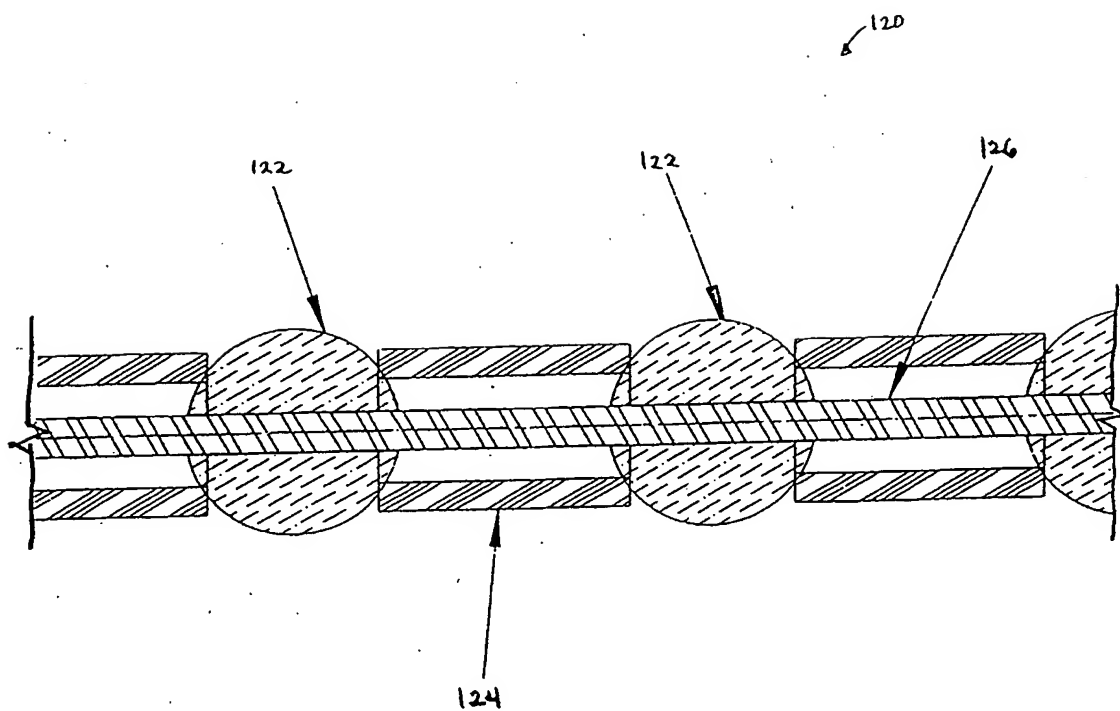


FIG. 10

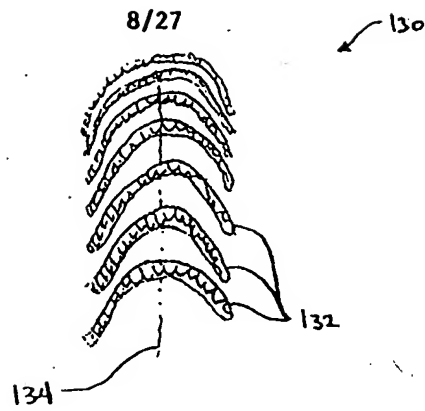


FIG. 11A

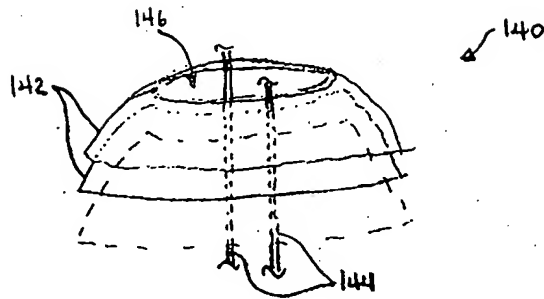


FIG. 11B

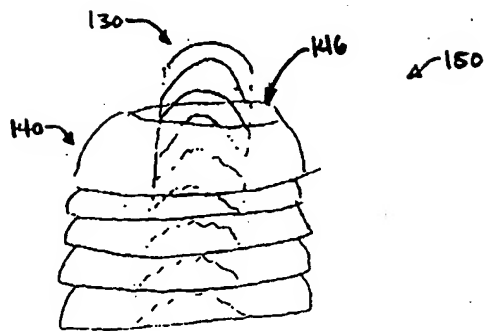


FIG. 11C

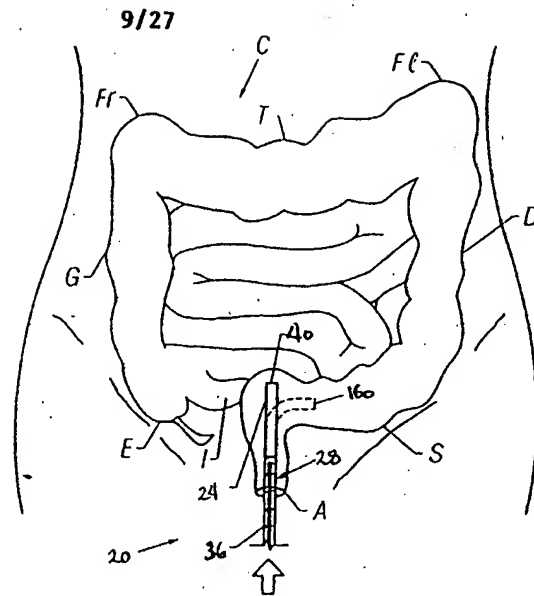


FIG. 12A

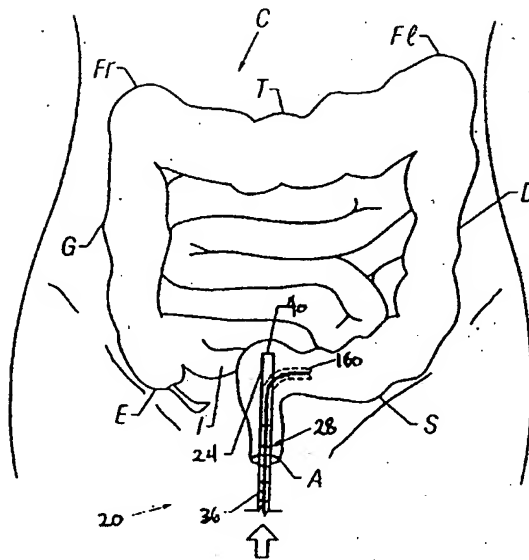


FIG. 12B

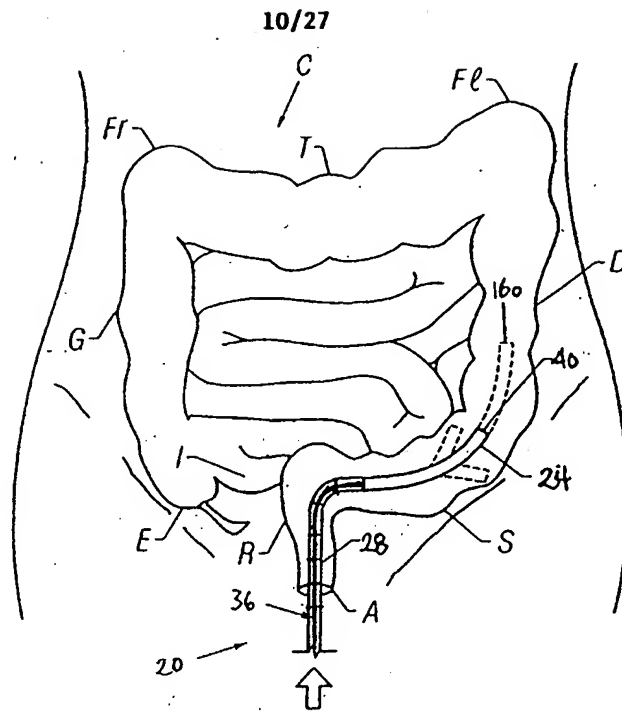


Fig. 12C

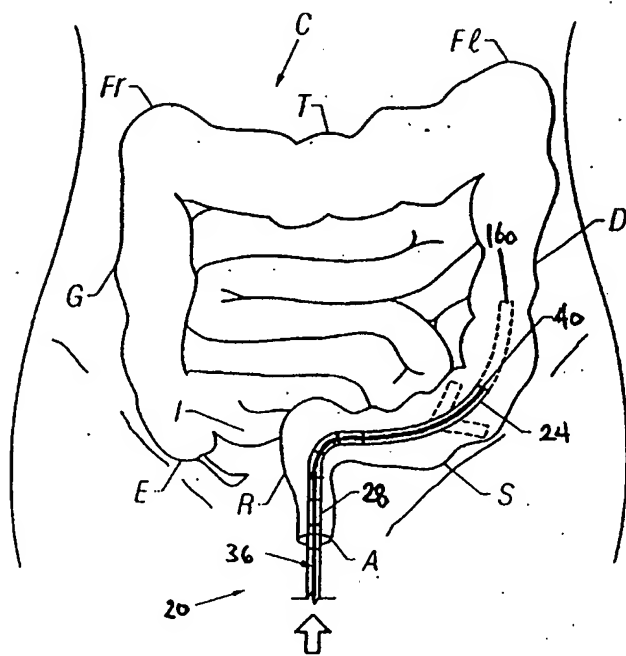


Fig. 12D

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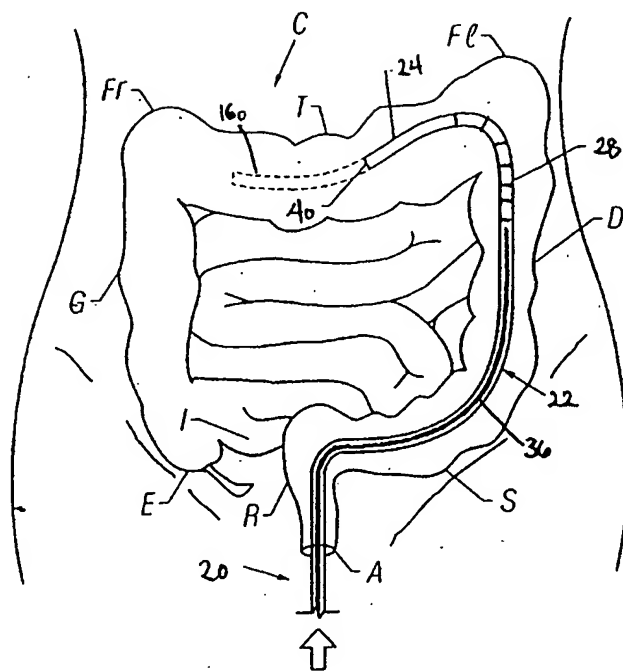


FIG. 12E

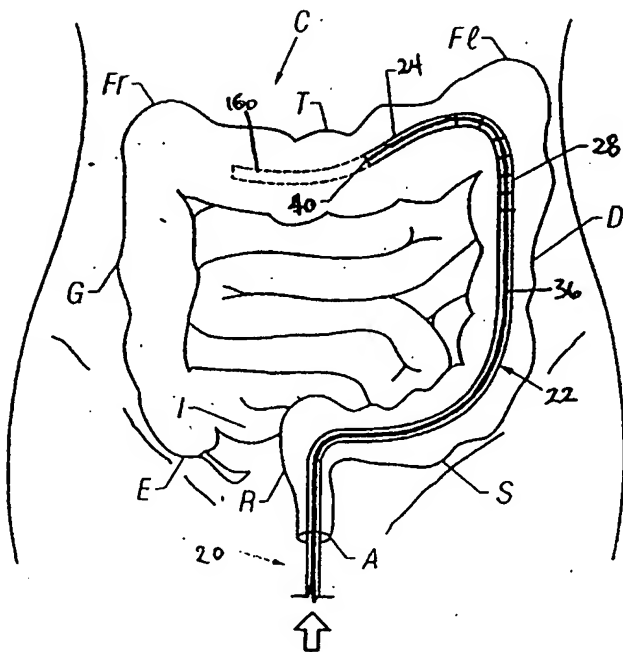


FIG. 12F



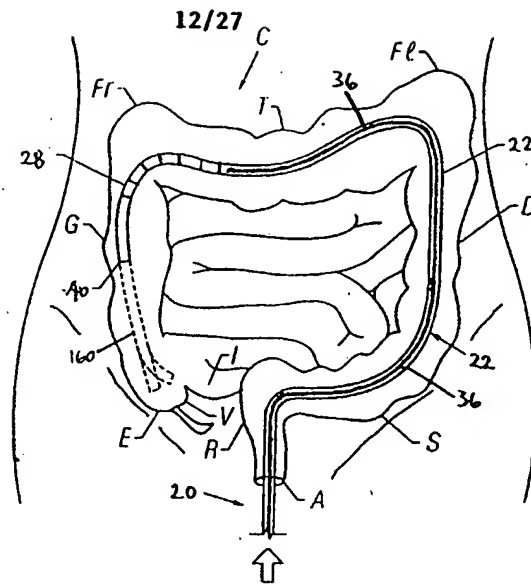


Fig. 12G

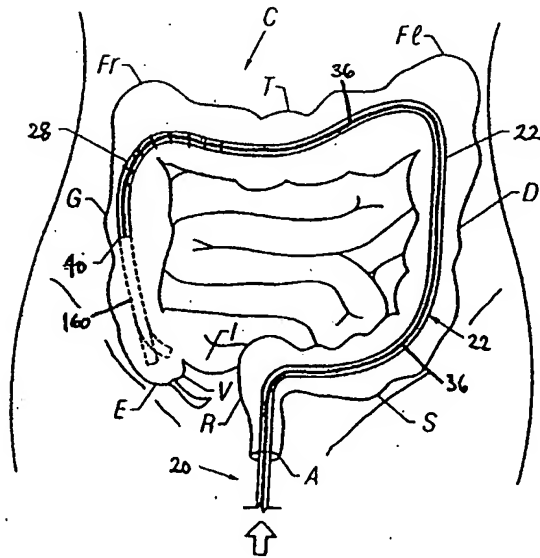


Fig. 12H

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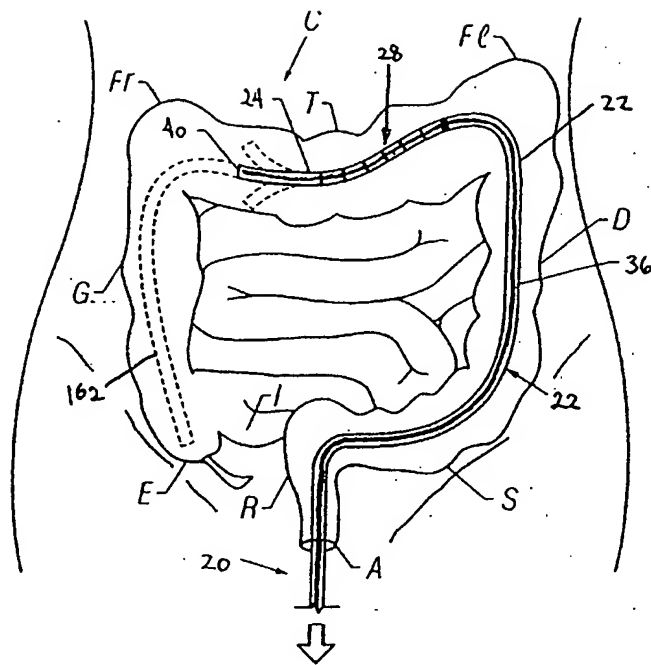


FIG. 13A

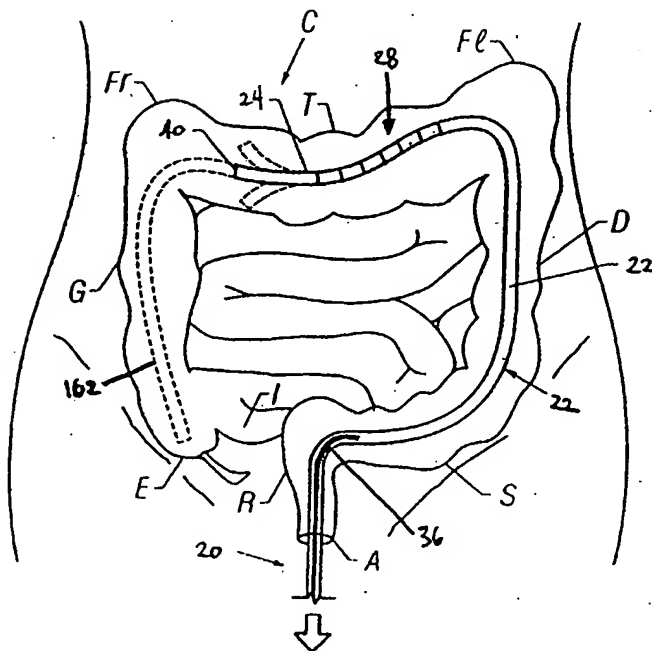


FIG. 13B

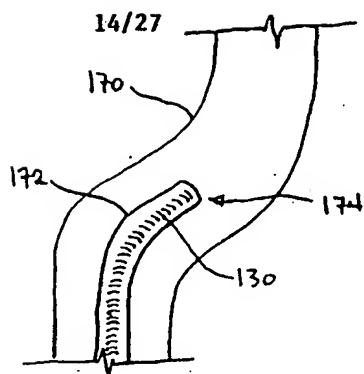


FIG. 14A

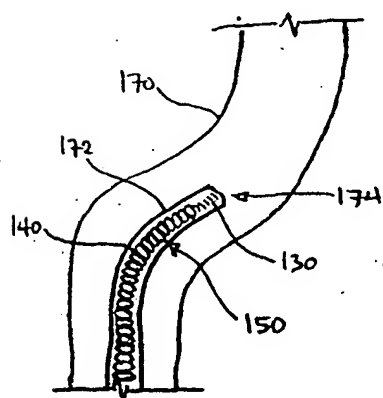


FIG. 14B

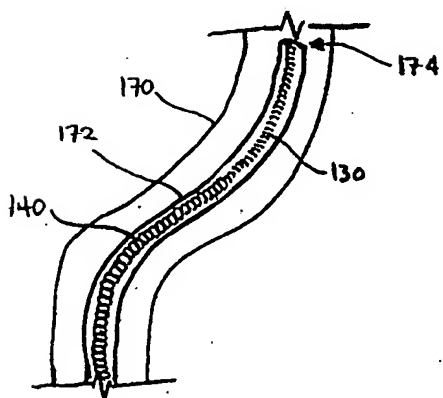


FIG. 14C

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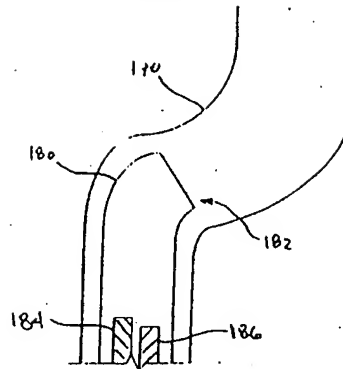


FIG. 15A

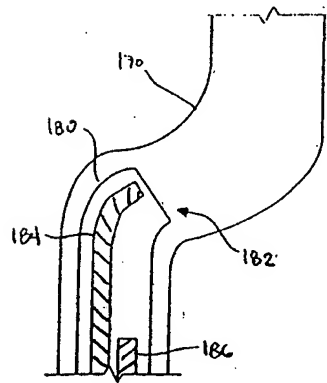


FIG. 15B

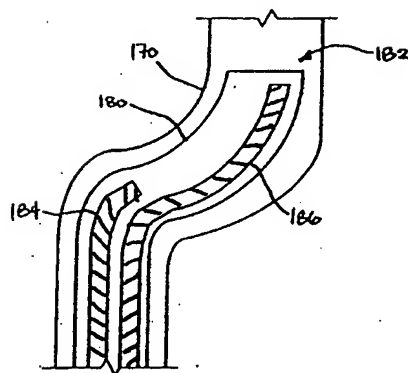


FIG. 15C

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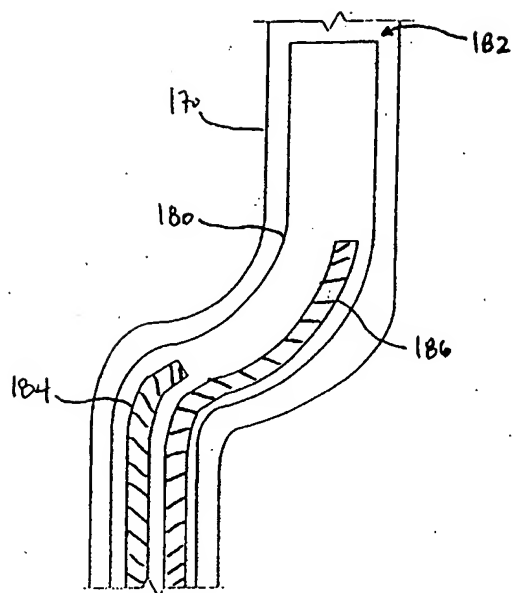


FIG. 15D

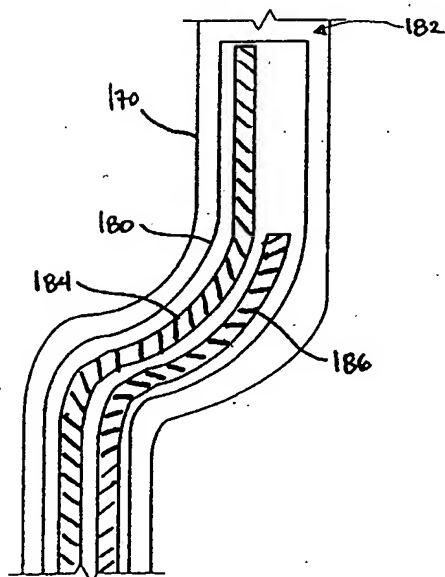


FIG. 15E

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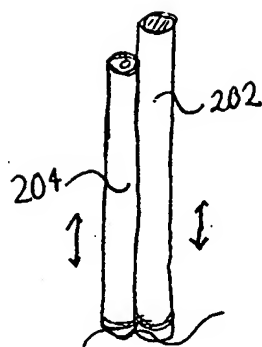


FIG. 16A

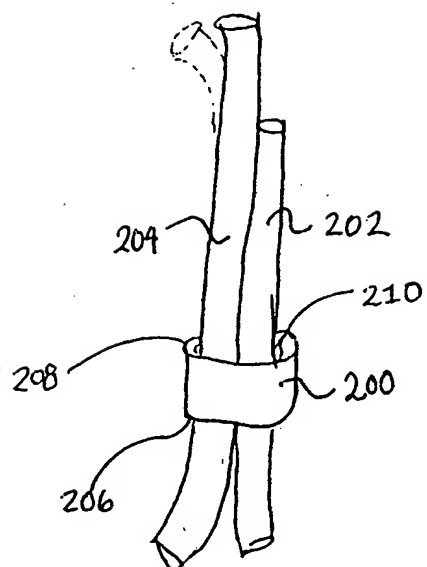


FIG. 16B

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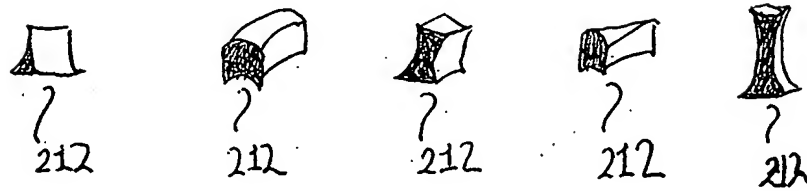
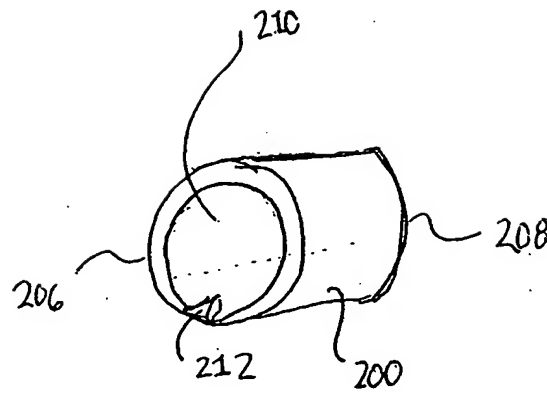


FIG. 16C



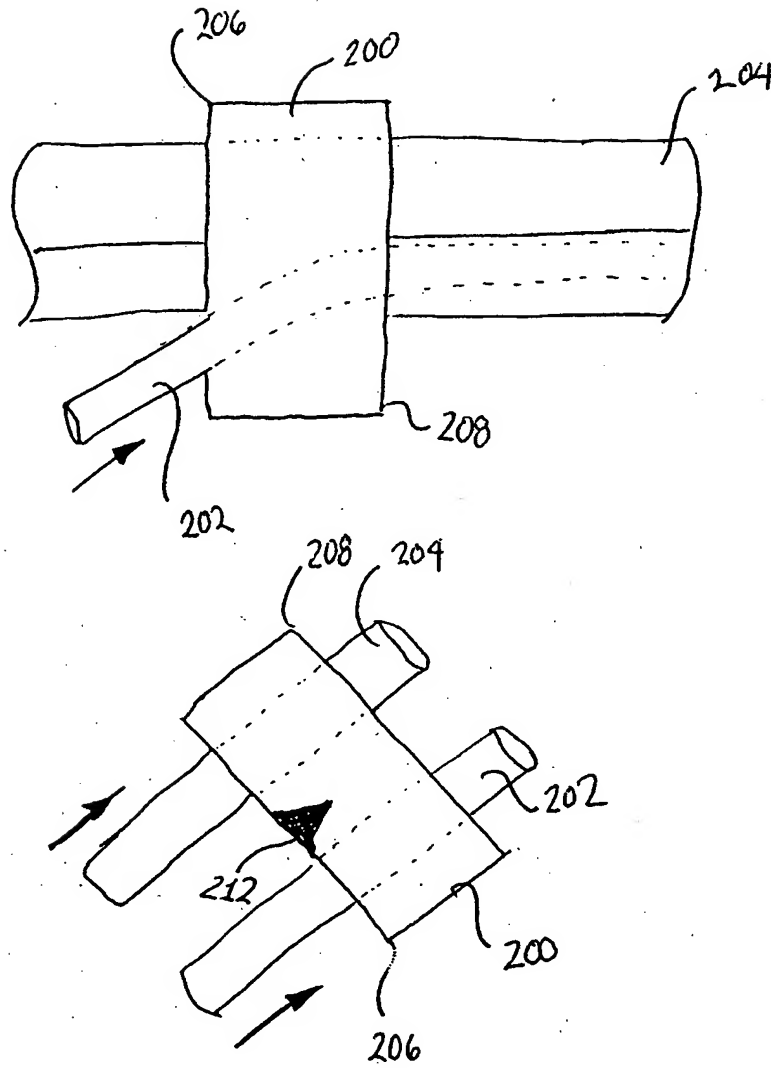


FIG. 16D

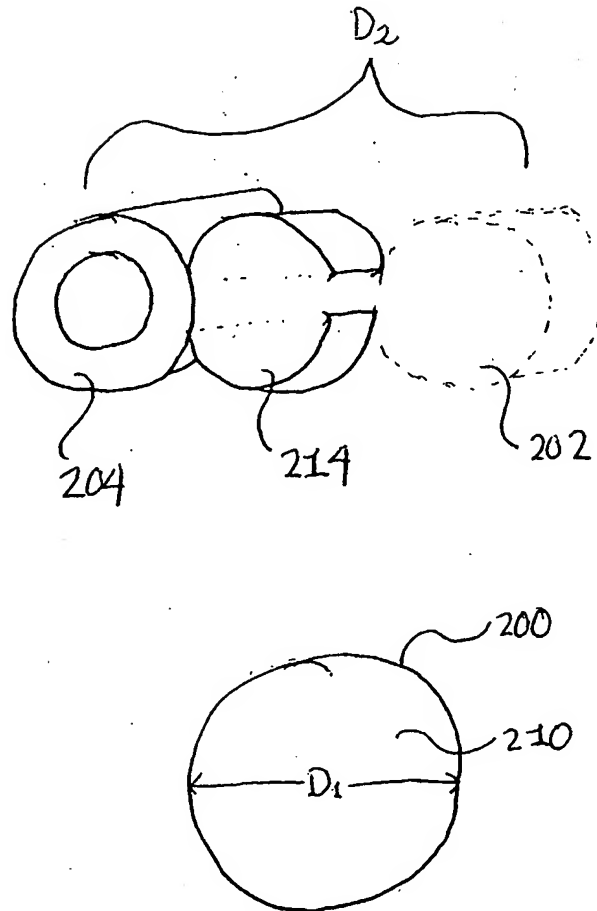


FIG. 16E

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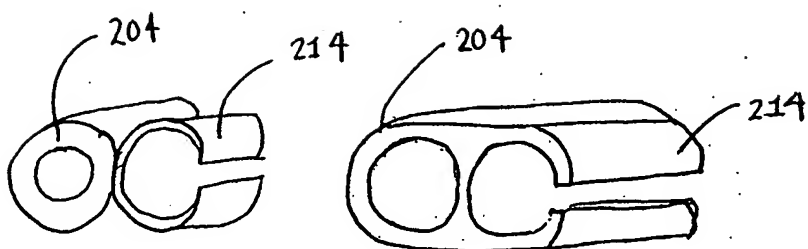


FIG. 17A

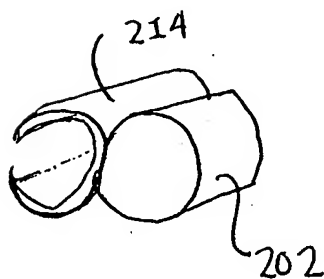


FIG. 17B

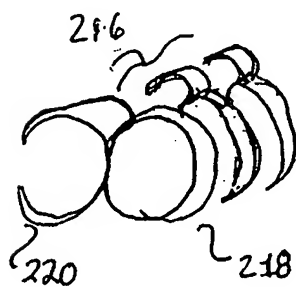


FIG. 17C

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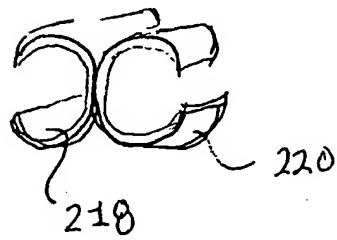
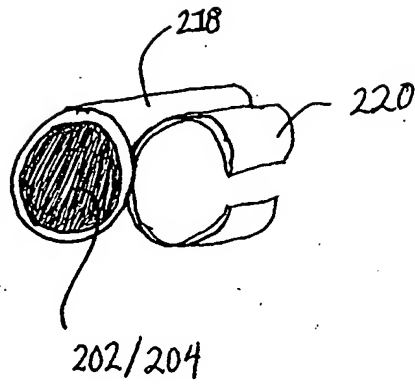


FIG. 17D

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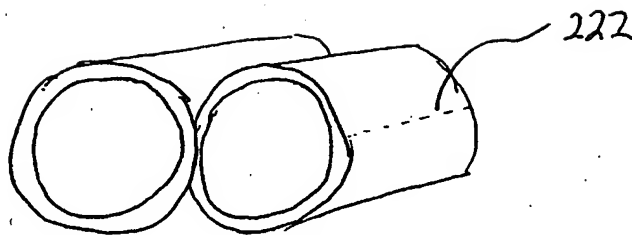


FIG. 17E

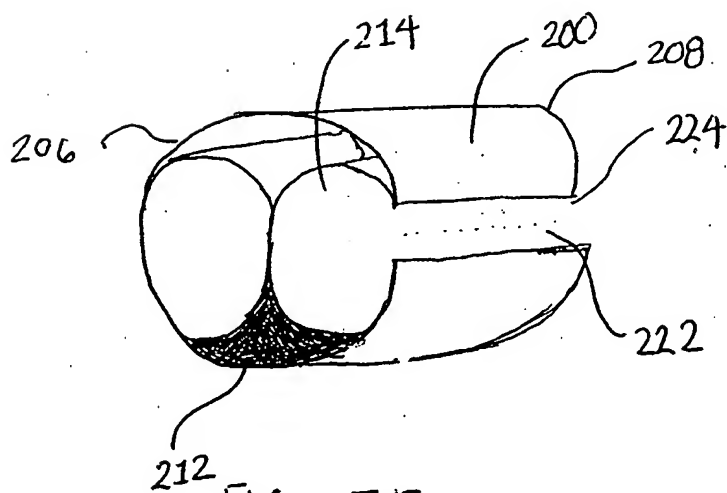


FIG. 17F

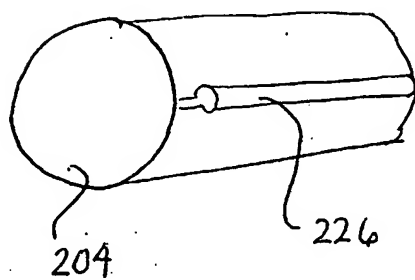
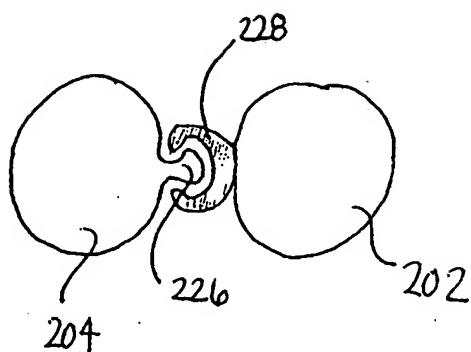
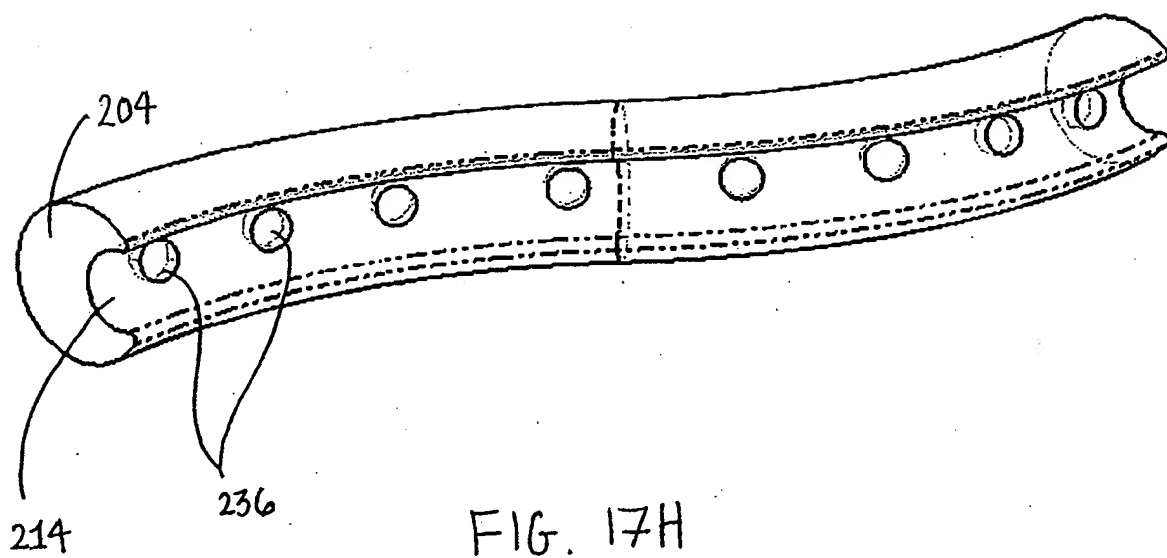


FIG. 17G



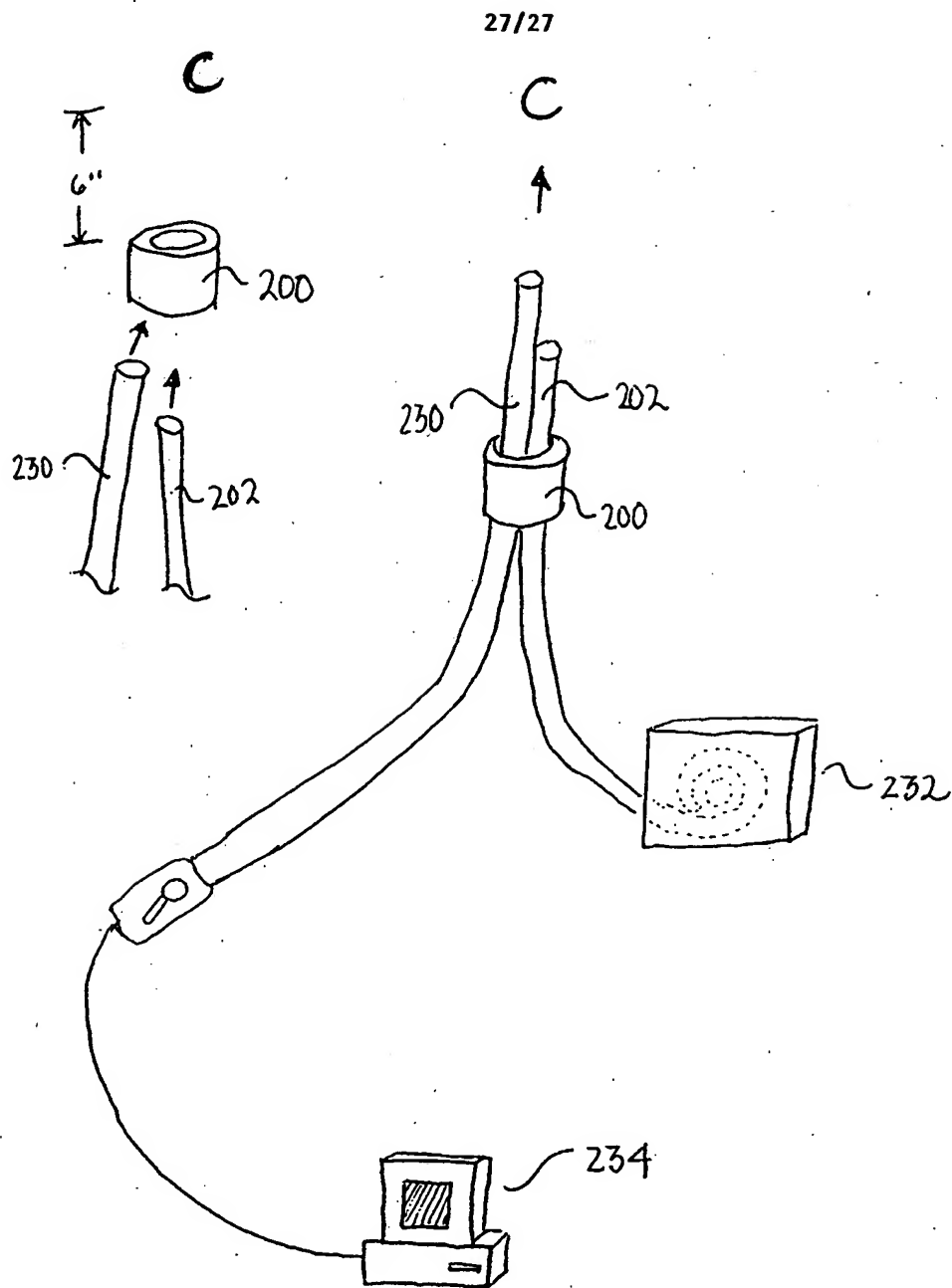


FIG. 18